U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
Public Health Service
Substance Abuse and
Mental Health Services
Administration

Center for Substance Abuse Treatment

State Methadone Treatment Guidelines

Treatment Improvement Protocol (TIP) Series

1

State Methadone Treatment Guidelines

Treatment Improvement Protocol (TIP) Series

1

Mark W. Parrino, M.P.A.
Consensus Panel Chair

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment

Rockwall II, 5600 Fishers Lane
Rockville, MD 20857

This publication was written under purchase order number 91MF358084 and under contract number 270-91-004 from CSAT (formerly the Office for Treatment Improvement). Robert Lubran, M.S., M.P.A., served as the Government project officer.

DHHS Publication No.
(SMA) 93-1991
Printed 1993.

Contents

What Is a TIP?

CSAT Treatment Improvement Protocols (TIPs) are prepared by the Quality Assurance and Evaluation Branch to facilitate the transfer of state-of-the-art protocols and guidelines for the treatment of alcohol and other drug (AOD) abuse from acknowledged clinical, research, and administrative experts to the Nation's AOD abuse treatment resources.

The dissemination of a TIP is the last step in a process that begins with the recommendation of an AOD abuse problem area for consideration by a panel of experts. These include clinicians, researchers, and program managers, as well as professionals in such related fields as social services or criminal justice.

Once a topic has been selected, CSAT creates a Federal resource panel, with members from pertinent Federal agencies and national organizations, to review the state of the art in treatment and program management in the area selected. Recommendations from this Federal panel are then transmitted to the members of a second group, which consists of non-Federal experts who are intimately familiar with the topic. This group, known as a non-Federal consensus panel, meets for about 3 days, makes recommendations, defines protocols, and arrives at agreement on protocols. Its members represent AOD abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A chair for the panel is charged with responsibility for ensuring that the resulting protocol reflects true group consensus.

The next step is a review of the proposed guidelines and protocol by a third group whose members serve as expert field reviewers. Once their recommendations and responses have been reviewed, the chair approves the document for publication. The result is a TIP reflecting the actual state of the art of AOD abuse treatment in public and private programs recognized for their provision of high quality and innovative AOD abuse treatment.

This TIP, on State methadone treatment guidelines, is the first published by CSAT since a treatment improvement initiative began. It represents another step by CSAT toward its goal of bringing national leadership to bear in the effort to improve AOD abuse treatment.

Contributors

Phil Appel, Ph.D.
Research Associate
Gateway Job Corps
Brooklyn, New York

Andrea G. Barthwell, M.D.
Medical Director
Interventions
Chicago, Illinois

Lawrence S. Brown, Jr., M.D., M.P.H.
Senior Vice President
Addiction Research and
Treatment Corporation
Brooklyn, New York

Dorrie Burke, M.Ed.
Director of Community Relations
Albert Einstein College
of Medicine
Division of Substance Abuse
Bronx, New York

David R. Gastfriend, M.D.
Chief
Addiction Services
Massachusetts General Hospital
Boston, Massachusetts

Herman Joseph
Research Scientist
Bureau of Research and
Evaluation
New York State Office of
Alcoholism and Substance
Abuse Services
New York, New York

Karol Kaltenbach, Ph.D.
Director
Family Center
Assistant Professor of Pediatrics
and Psychiatry and Human
Behavior
Thomas Jefferson University
Philadelphia, Pennsylvania

Elizabeth Khuri, M.D.
Medical Director
Adolescent Development
Program
Cornell Medical Center
New York Hospital
New York, New York

Mary Jeanne Kreek, M.D.
Associate Professor and
Physician
The Rockefeller University
New York, New York

John Langrod, Ph.D.
Director of Admissions
Albert Einstein College
of Medicine
Division of Substance Abuse
Bronx, New York

Ira J. Marion, M.A.
Associate Executive Director
Albert Einstein College
of Medicine
Division of Substance Abuse
Bronx, New York

Susan F. Neshin, M.D.
Medical Director
Jersey Shore Addiction
Services, Inc.
Asbury Park, New Jersey

Mark W. Parrino, M.P.A.
President
American Methadone Treatment
Association, Inc.
New York, New York

J. Thomas Payte, M.D.
President
Drug Dependence Associates
San Antonio, Texas

Neil S. Silverman, M.D.
Medical Director
Family Center
Clinical Assistant Professor of
Obstetrics and Gynecology
Thomas Jefferson University
Philadelphia, Pennsylvania

Ronald J. Wapner, M.D.
Director
Division of Maternal-Fetal
Medicine
Professor of Obstetrics and
Gynecology
Thomas Jefferson University
Philadelphia, Pennsylvania

Joan Ellen Zweben, Ph.D.
Executive Director
East Bay Community Recovery
Project and 14th Street Clinic
Berkeley, California

Consensus Panel

Carol Addiss
Substance Abuse Program Manager
Mental Health Services
Riverside, California

Dennis Baker
Director of Food and Drug
Texas Department of Health
Austin, Texas

Sally S. Brown, Ph.D
Associate Director of Project Reality
Salt Lake City, Utah

Richard Christensen, P.A., C.A.S.
Director of Medical Services
Valle del Sol, Inc.
Phoenix, Arizona

Michael D. Couty
Deputy Director
Field Services
Department of Mental Health
Division of Alcohol and Drug Abuse
Jefferson City, Missouri

Mike Ezzell
Director
Program Compliance Division
Texas Commission on Alcohol and Drug Abuse
Austin, Texas

John W. Farrell
Acting Assistant Commissioner
Division of Alcoholism, Drug Abuse and Addiction Services
Trenton, New Jersey

John Flint, M.D.
Medical Director
Operation PAR, Inc.
St. Petersburg, Florida

David R. Gastfriend, M.D.
Chief
Chemical Dependence Programs
Massachusetts General Hospital
Boston, Massachusetts

Marlene J. Hiller
Clinical Administrator
Addiction Research and Treatment Services
Denver, Colorado

Mary Jeanne Kreek, M.D.
Associate Professor and Physician
The Rockefeller University
New York, New

Richard H. Lane
Executive Director
Man Alive Research, Inc.
Baltimore, Maryland

Ira Marion, M.A.
Associate Executive Director
Albert Einstein College of Medicine
Division of Substance Abuse
Bronx, New York

Susan F. Neshin, M.D.
Medical Director
Jersey Shore Addiction Services, Inc.
Asbury Park, New Jersey

Mark W. Parrino, M.P.A.
President
American Methadone Treatment Association, Inc.
New York, New York

J. Thomas Payte, M.D.
President
Drug Dependence Associates, Inc.
San Antonio, Texas

John Perez
Downstate Coordinator
New York State Office of Alcoholism and Substance Abuse Services
Program and Quality Care Review Unit
New York, New York

Janet Rogers
Vice President for Development and Evaluation
STEP ONE, Inc.
Winston-Salem, North Carolina

Johnie L. Underwood
Deputy Commissioner
Division of Addiction Services
Indiana Department of Mental Health
Indianapolis, Indiana

Ellen Weber, J.D.
Legal Action Center
Washington, DC

John Willson
State Methadone Authority
Office of Substance Abuse Services
Michigan Department of Public Health
Lansing, Michigan

George E. Woody, M.D.
Chief of Psychiatry
Substance Abuse Treatment Unit
Philadelphia Veterans Affairs Medical Center
Philadelphia, Pennsylvania

Joan Ellen Zweben, Ph.D.
Executive Director
14th Street Clinic
East Bay Community Recovery Project
Berkeley, California

Foreword

Under the sponsorship of the Center for Substance Abuse Treatment (CSAT), the American Methadone Treatment Association, Inc., in conjunction with the American Society of Addiction Medicine's Committee on Methadone Treatment, has developed these practical treatment guidelines. The guidelines shall serve as a blueprint for State policy officials and methadone maintenance treatment providers. They present the state-of-the-art in effective therapeutic techniques for methadone maintenance treatment. Publication of the guidelines comes at a time of considerable activity in the treatment system, which is currently driven by HIV-spectrum disease, multidrug-resistant TB, polydrug abuse, a recession-impacted economy, and a need for enhanced program accountability. Methadone maintenance treatment programs and, most importantly, the patients they serve, will be the ultimate beneficiaries of these guidelines.

Methadone maintenance treatment has come under increased scrutiny over the past several years. The White House Conference for a Drug Free America issued its Final Report, published in June 1988, recommending that an independent organization evaluate the efficacy of methadone maintenance treatment. This report also recommended developing standardized, objective outcome measures for assessing the success of drug treatment programs. The General Accounting Office Report on Methadone Treatment, published in March 1990, found significant differences in the effectiveness of methadone maintenance treatment programs. In fact, some of the treatment programs reviewed in the report demonstrated continued heroin use in their patient populations as a direct result of prescribing subtherapeutic methadone maintenance doses. The pharmacology of methadone has been exhaustively researched and its safety and efficacy proven.

In meeting the challenges of both today and tomorrow, this nation's methadone maintenance treatment programs must incorporate what the scientific community has demonstrated to be effective treatment practices. As the contributing authors have indicated, the methadone maintenance treatment system, including States and treatment providers, faces challenges and issues not included on the agenda when methadone maintenance emerged as a treatment modality some 20 years ago. There will continue to be pressure from Congress, funding sources, regulators, and the public for fiscal and programmatic accountability. My vision for CSAT includes fashioning a comprehensive treatment system to link methadone maintenance treatment with the primary medical care, public health, mental health, and social service systems; and to ensure that Federal treatment resources are appropriately targeted, based on lessons learned from relevant science-based research and technical assistance initiatives.

The Center for Substance Abuse Treatment is committed to enhancing the quality and integrity of this country's methadone maintenance treatment system. These guidelines represent a significant part of this commitment, which also includes provision of individualized technical assistance to the States and development of additional, forward-thinking policy initiatives.

Lisa W. Scheckel
Acting Director
Center for Substance Abuse Treatment

Note From the Chair

I want to thank each of the contributing authors for sharing their experience and insights with their colleagues; in addition, I am thankful for the support of the Methadone Treatment Committee of the American Society of Addiction Medicine. The Single State Agencies and the National Association of State Alcohol and Drug Abuse Directors were also extremely helpful in sharing their concerns and recommendations, making these guidelines balanced and meaningful.

It is also important to cite the extraordinary work of the many individuals who provided the technical support in organizing meetings and editing, designing, and formatting this precedent-setting document. A complete listing of these individuals is provided in appendix F.

Finally, I wish to acknowledge the work of all the people who reviewed these guidelines through each level of the consensus-building process. The direct involvement of Federal and State agency officials with methadone treatment providers in developing these guidelines has helped to strengthen the integrity of the final document.

Mark W. Parrino, M.P.A.

Acronyms

AA	Alcoholics Anonymous
ADM disorder	alcohol, drug, and mental health disorder
AIDS	acquired immune deficiency syndrome
AS	abstinence syndrome
ASAM	American Society of Addiction Medicine
ASI	Addiction Severity Index
ASP	antisocial personality
AZT	azidothymidine
CARF	Commission on Accreditation of Rehabilitation Facilities
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CNS	central nervous system
CSAT	Center for Substance Abuse Treatment
DEA	Drug Enforcement Administration
DHEW	Department of Health, Education and Welfare
DIS	Diagnostic Interview Schedule
DSM-IIIR	Diagnostic and Statistical Manual of Mental Disorders, third edition, revised
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
EIA	enzyme immunoassay
FDA	Food and Drug Administration
GAO	General Accounting Office
GC/MS	gas chromatography/mass spectrometry
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HUD	(Department of) Housing and Urban Development
ICHD	intracranial hemidiameter
IDUs	injecting drug users
IND	Investigational New Drug
INH	isoniazid
IV	intravenous
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
LAAM	levo-alpha-acetyl-methadol
MDI	Bayley Mental Development Index
MDR TB	multidrug-resistant tuberculosis
MMTP	methadone maintenance treatment program
MTA	methadone to abstinence
MTQAS	Methadone Treatment Quality Assurance System
NA	Narcotics Anonymous
NAPAN	National Association for the Prevention of Addiction to Narcotics
NIDA	National Institute on Drug Abuse
NIMH	National Institute of Mental Health
NK cell	natural killer cell

OEO . . . . . Office of Economic Opportunity
ONDCP . . . . . Office of National Drug Control Policy
OSHA . . . . . Office of Safety and Health Administration
PCP . . . . . *Pneumocystis carinii* pneumonia
PDI . . . . . Motor Development Index
PPD . . . . . purified protein derivative
RIA . . . . . radioimmunoassay
RPR . . . . . rapid plasma reagent
SAMHSA . . . . . Substance Abuse and Mental Health Services Administration
SAODAP . . . . . Special Action Office for Drug Abuse Prevention
SMA . . . . . State Methadone Authority
SSA . . . . . Single State Agency
STDs . . . . . sexually transmitted diseases
TB . . . . . tuberculosis
THC . . . . . tetrahydrocannabinol
TLC . . . . . thin-layer chromatography
VA . . . . . Department of Veterans Affairs
VDRL . . . . . Venereal Disease Reference Laboratory

Executive Summary

Chapter 1—Overview: Current Treatment Realities and Future Trends

The 1990s will be critical for methadone maintenance treatment and the entire substance abuse prevention and treatment system. There will be a more sustained regulatory presence at the Federal and State levels, which will work in tandem with legislative oversight. We are entering an era of greater accountability that will see the implementation of standardized, performance-based outcome measures.

Treatment personnel require enhanced training to respond to issues of serious medical illness and death. Methadone maintenance providers will be under greater pressure to offer a richer mix of comprehensive services. Peer support groups will become a permanent part of the treatment system. More medical care will be offered at the clinic site as programs create better primary health care linkages to the mainstream medical communities. Vocational referral and job placement will become more critical treatment components as outcome measures are used to evaluate treatment success and as incentives are built into third-party insurance packages. More programs will begin to address the tragic realities of intergenerational drug abuse by implementing parenting skill workshops at or through the treatment setting.

Treatment resources can be more efficiently used as more policy-driven research indicates how to choose the best mix of personnel for treating patients at different phases of their care. The annual cost of providing these services should be realistically determined through credible planning initiatives by State officials, with direct input from methadone maintenance providers.

The challenges of this decade can only be met and overcome through the spirit of mutual respect between regulatory officials, methadone maintenance treatment providers, and patients. Patients can only do well in a therapeutic environment with access to caring and competent staff. The work of staff must be supported in action and spirit by program management. In turn, responsible program management should be supported through thoughtful Federal and State policy initiatives. The methadone maintenance treatment system should be strengthened and improved if it is to care more effectively for less healthy people.

Recommendations

- Offer comprehensive medical and counseling services on-site to respond to the immediate needs of the present patient population, and develop an effectively managed network of ancillary referral services.
- Plan medical, case management, and counseling caseload numbers around the specific needs of the program's patient population.
- Configure caseloads to provide better access to HIV counseling and intensive clinical support for active alcohol- and drug-using patients.
- Encourage patient peer support and self-help groups to meet in methadone maintenance programs.
- Take patient loitering seriously; prevent loitering by having well-established policies that are integral to the treatment process and are maintained by a well-managed and stable security complement.
- Educate the public about the value of methadone maintenance treatment.
- Use cooperative "good neighbor" projects, open houses, and educational forums to more effectively engage the community.
- Seek to use treatment resources more efficiently; this goal will become more achievable as policy-driven research increasingly suggests how to use the best mix of personnel in treating patients at different phases of their care.

- Develop different models of care that respond to individual patient needs during different phases of the methadone maintenance treatment experience. Newly admitted patients will require ready access to a broad range of services, while successfully stabilized patients who have been maintained on methadone for several years may require less intensive services.

Chapter 2—Historical Perspectives and Public Health Issues

This chapter reviews the social transformation that occurred within the United States during the past century that placed disparate social groups at risk for dependence on narcotics. Major events intertwined with this transformation were the adoption of the Harrison Act, the antimaintenance stand taken by the Department of the Treasury as an interpretation of this act and the legal challenges that resulted, the subsequent period of prohibition of opiate maintenance within medical practice, and later, the development of methadone maintenance as a treatment modality for narcotic addiction. This chapter describes the conceptual basis of methadone maintenance, its medical safety, its program effectiveness as a public health intervention to curtail transmission of HIV, and its central role in the treatment of heroin addiction. Finally, the chapter discusses the urgent need to improve the quality of MMTPs and the need for education and outreach at all levels of society to counteract harmful myths about the modality.

Chapter 3—Review of Clinical Issues

This chapter reviews some of the major issues facing treatment providers in MMTPs. Harvesting the enormous benefits of advances in our understanding of how to improve treatment will require committing adequate resources and being willing to use our knowledge to revise policies and regulations. Accountability systems should be modernized and streamlined to provide a consistent standard of care without excessively restricting clinicians. The regulatory stance needs to be one that encourages rather than penalizes programs willing to tackle difficult clinical problems. A major training effort is needed to counteract counselor demoralization and to upgrade skills to better address counselors' myriad, complex tasks. More specialized resources, such as highly trained psychotherapists, need to be selectively used for patients with coexisting ADM disorders. Strategies for addressing continued heroin, alcohol, and other drug use should be refined. Greater efforts are needed to address the complex needs of women in treatment, particularly pregnant women, and to provide services such as child care to reduce barriers to women's extensive participation in treatment. A growing number of patients with HIV-spectrum disease need services to respond to their unique needs; these services should be integrated into the program as a whole. Methadone maintenance treatment is relatively unique in that staff see patients regularly over a long period; support systems must be strengthened to help staff cope with the increasing number of terminally ill patients. Programs should explore ways of integrating self-help programs, with sensitivity to the complexities of this task. Patients who wish to discontinue methadone maintenance should be assisted from the perspective that their lifestyle changes are the top priority, and the issue of getting off methadone is less important than preserving those gains. Staff should be provided with training appropriate to the unique requirements of MMTPs.

A long-term plan and a secure commitment of resources are essential to achieve the goals delineated in this chapter. Although the task is great, the combination of our clinical experience and ample empirical investigation to clarify the nature of narcotic addiction and to identify effective treatment elements give us new possibilities for achieving our goals.

Recommendations

- Review existing State regulations to determine if they actually produce their intended effect, and reduce barriers to attracting and retaining patients in treatment, e.g., child care.
- Augment resources, including technical assistance, available to MMTPs.
- Ensure that patients receive comprehensive clinical assessments and that treatment plans are individualized and contain short- and long-term goals; specify the level, duration, and frequency of counseling; and record events that trigger changes in those arrangements.
- Seek to simplify recordkeeping, decrease staff time devoted to paperwork, and improve the quality of documentation.
- Develop protocols to monitor the use of alcohol and other drugs and the productive activity of long-term patients so that these patients can be seen in a medical maintenance model; incorporate

mechanisms that identify signals of potential relapse.
- Provide supplemental professional psychotherapy for patients with coexisting psychiatric disorders, coordinate drug counseling with professional psychotherapy, and ensure patient access to physicians with knowledge of appropriate prescribing practices for an addicted population.
- Provide patients with access to vocational evaluation, referral, training programs, and parenting workshops.
- Make every effort to retain patients in treatment. It is rarely appropriate to discharge patients for manifesting behaviors characteristic of addictive disorders; therefore, consider discharge only when all other alternatives have been exhausted and when it is clear that discharge constitutes the lesser harm.
- Implement activities that deemphasize the role of intoxicants (not just heroin) in patients' lives and focus on the importance of drug- and alcohol-free lifestyles in achieving positive treatment outcomes.
- Address issues that may be of particular concern to women, including intimacy, prevention of HIV and other STDs, child care, pregnancy, and family planning.
- Integrate AIDS-related activities and assistance in handling the multiple aspects of HIV-spectrum disease into methadone maintenance treatment; provide staff support and specialized recovery groups for patients affected by HIV and their families.
- Encourage patients to participate in self-help programs when appropriate for the patient and when programs are available that are hospitable to methadone-maintained patients.
- Assist those patients who wish to discontinue methadone use in addressing personality patterns, interpersonal issues, family issues, job skills, friendship patterns, health practices, recreational activities, and other issues that could lead to relapse.
- Develop and implement counselor and physician education activities and methods for disseminating information about pharmacological and other advances.

Chapter 4—Admissions Policies and Procedures

The admissions process is probably the most important stage of methadone maintenance treatment because it begins the individual's transition from street addict to methadone maintenance patient. It is the first point at which the individual is exposed to the treatment system, and the available services, rules, and requirements. What occurs at this stage will shape the patient's attitudes, concerns, and motivations throughout treatment. Thus, this experience must be a positive one that engages the patient, assesses major problems and needs, and lays the groundwork for ongoing clinical intervention.

MMTP admissions policies should ensure that patients are admitted into treatment humanely and rapidly and that program practices facilitate socializing the patient into the treatment system. Applicant screening should be extensive and thorough and should form the basis for effective, long-term treatment planning. While determining eligibility for treatment, staff should ensure that methadone maintenance is the most appropriate form of treatment, that the admission is voluntary, and that the patient understands the risks, benefits, and options available. Proper patient orientation is instrumental to the therapeutic nature of the admissions process. Admissions procedures should not unduly delay the patient's admission.

Discharge from treatment should be based on sound clinical practices, with the best interests of both the patient and the program considered. Continuity of care should be considered and referral to more suitable programs should be the rule. Due process and attention to patient rights ensure that discharge practices are not abusive or arbitrary. Programs should form liaisons with other MMTPs and other treatment modalities to facilitate the continuity of care.

Recommendations

- Ensure that physical surroundings are welcoming, conducive to rehabilitation, and clearly distinct from the hostile environment in which many addicts live.
- Encourage individuals working in the admissions unit to be sensitive to patient needs, and ensure that they reflect, when possible, the population being served.
- Admit patients to treatment rapidly; facilitate the socialization of the patient into the treatment system.
- Offer priority placement to pregnant women and people with serious medical and/or psychiatric problems.
- Provide thorough patient screening and assessment that forms the basis for effective treatment planning.
- Screen patients for high-risk behaviors related to HIV, STDs, multidrug-resistant TB, and other infectious diseases.
- Ensure during the screening process that methadone maintenance is the most

appropriate treatment modality and that treatment is not coerced.
- Provide patients with a proper orientation to the program, its policies and procedures, and patient rights and responsibilities.
- Discharge patients with considerable caution; attempt to refer patients to a more suitable treatment modality.

Chapter 5—Principles of Methadone Dose Determination

Since the early recommendation by Dole and Nyswander (1966) of methadone maintenance doses of 80–120 mg daily, methadone dose practice has been more often determined by politics and philosophy than by rational data or good clinical judgment. Studies reported by D'Aunno and Vaughn (1992) show that more than 50 percent of patients nationwide receive suboptimum methadone doses that are inadequate to prevent continued illicit narcotic use. Other studies have shown that adequate methadone doses, individually and clinically determined, correlate with reduced illicit drug use and improved patient retention in treatment. Perhaps the terms low dose and high dose should be discarded entirely in favor of "adequate dose." It is clear that methadone dose determination should always be a matter of good clinical judgment on the part of the experienced physician who has the advantage of having the patient in front of him or her. The establishment of therapeutic doses of methadone, as in the case of any other medication, is not a suitable matter to be decided by regulatory agencies or legislative policy.

The immediate goal of methadone dosing is to relieve any signs and symptoms of abstinence syndrome. After full relief is established, the induction process may be continued at a slower pace in order to reach a therapeutic maintenance dose. During the maintenance phase, some patients may remain on the same dose for years, while others may require periodic adjustments. Both methadone dose determination and periodic adjustments necessitate careful clinical judgment, including looking for signs of overmedicating and undermedicating patients. Staff and patients should be aware of the risks associated with relapse to injecting drug use when considering withdrawing or tapering of the methadone dose.

This chapter also explores the basic principles of managing pain in methadone maintenance patients and addresses the common misconceptions regarding approaches to adequate pain management for methadone patients undergoing medical procedures. In addition, chronic pain management issues are explored.

Recommendations

- Determine methadone dose on the basis of good clinical judgment by an experienced physician who has examined the patient; dose is not a suitable matter to be decided by regulatory agencies or legislative policy.
- Provide methadone doses that are enough to produce the desired response in the patient for the desired duration of time, with an allowance for a margin of effectiveness and safety. The majority of patients will ultimately fall into a range of effective doses, with the low end of the range being about 50 mg and the high end at 120 mg; for most patients, the effective dose is likely to be about 80 mg, plus or minus 20 mg.
- Ensure that history and physical examination support a judgment on the part of the physician that the patient is a suitable candidate for methadone maintenance treatment.
- Base the initial dose on the physician's evaluation of the history and present condition of the patient, with added knowledge of local conditions, such as the relative purity of the available street drugs.
- Determine the maintenance dose individually, with careful and caring attention to the essential information provided by the patient; the dose should be determined by an experienced physician and should be adequate to achieve the desired effects for 24 hours or more, with an allowance for day-to-day fluctuations and elimination.
- Continue methadone maintenance as long as desired by the patient and as long as benefit is derived from treatment.
- Avoid manipulating doses either up or down to reinforce positive or punish negative behavior.
- Manage pain by the use of selected short-acting opioid agonist drugs; relief can often be attained by using higher doses at more frequent intervals.
- Attempt withdrawal only when strongly desired by the rehabilitated patient.

Chapter 6—Urinalysis as a Clinical Tool

Urinalysis is a critical component of methadone maintenance treatment. Originally used as a measure of program effectiveness, urine screening is now used to make programmatic decisions, to monitor drug use, and to decide whether the patient is responsible enough to receive take-home medication. Urinalysis reports are used by

regulatory authorities to monitor whether programs are providing take-home doses to appropriate patients or to patients who may sell or divert them to the illicit market.

Urine screening methods vary widely from program to program and from region to region. Methadone maintenance programs should develop urine screening policies and procedures to complement patient treatment and be cognizant of the inevitable tension involved in monitoring urine and using the reports for treatment decisions. These urine screening programs should be implemented with concern for the patient's dignity and privacy and be consistent with good clinical care.

Recommendations

- View Federal urinalysis requirements as minimal and regulatory; evaluate clinical needs and develop policies and procedures to integrate urinalysis into treatment planning and clinical practice.
- Obtain urine specimens in a treatment atmosphere that suggests a sense of trust and safety, rather than punishment and power.
  - Obtain specimens randomly on the basis of the patient's clinic visit schedule.
  - Inform patients about how urine specimens are collected and of the responsibility to provide a specimen when asked.
  - Ensure that the bathroom used for collection is clean and always supplied with soap and toilet articles.
  - Collect specimens in a manner that minimizes falsification; if using direct observation, carry it out ethically, with respect for patient privacy.
- Discuss positive urine results with the patient, and document these results in the clinical case record; also record the patient's response.
- Provide counseling, casework, medical review, and other interventions when continued use of drugs is a treatment problem; punishment is not appropriate.
- Take seriously the patient's adamant denial of drug use, and investigate the possibility of a false positive.
- Review dosage when positive urine reports for heroin and other illicit drugs are obtained, and provide substance abuse and HIV counseling; evaluate carefully reports that are negative for methadone.
- Monitor urine reports to ensure compliance with State and Federal regulations, discover trends in drug use that may require a redirection of clinical and fiscal resources, ensure that positive urine reports are addressed appropriately by staff, and ensure that reports and responses are documented in the case record.
- Ensure that the frequency of urine screenings is clinically appropriate for each patient and allows for a concerned and rapid response to the possibility of relapse.
- Perform urine screens with sufficient frequency so that they can be used to assist in making informed decisions about take-home privileges; however, programs should not make clinical decisions based solely on these reports.
- Evaluate the quality of the laboratory that is selected to perform urine screens, the laboratory's use of proper equipment, methodology, and quality control; also ensure use of quality standards by all involved in the screening.
- Properly train and educate regulatory and program staff about the tests and procedures used by the MMTP so that their benefits and limitations can be understood.

Chapter 7—Responsible Take-Home Medication Practices

Take-home medication is an important clinical tool in methadone maintenance treatment. A number of factors are important in attempting to strike an appropriate balance between the beneficial effects and the negative consequences of take-home medication. Critical factors to consider include how long the patient has been enrolled in treatment, the presence of physical or psychological signs of drug withdrawal, the existence and severity of a concurrent medical disorder, the presence of behavioral issues, the appropriateness of the home environment, and the rehabilitative potential of this approach for the given patient. This chapter discusses the general principles regarding clinical indications for take-home medication and for monitoring patients who receive take-home medication.

The boundaries governing the use of take-home methadone are both stipulated in Federal regulations and further refined by the regulations of many State drug abuse and public health agencies. However, these regulations offer sufficient latitude so that MMTPs can make the clinically relevant decisions about the merits and drawbacks of using this invaluable clinical tool for their individual patients. The decision regarding take-home methadone for patients should take into account medical, psychological, behavioral, and social issues.

Recommendations

- Use a team of representatives from the appropriate disciplines (e.g., physicians, nurses, and

counselors) to accumulate and discuss the necessary information regarding take-home medication for each patient.
- Do not use the level of the daily dose to determine whether a patient should receive take-home medication.
- Consider the following factors in supporting initiation of take-home medication: Sufficient length of time in treatment, attainment of clinical stability, progress in rehabilitation, medical necessity, behavioral factors, and emergency circumstances.
- Consider the following factors as arguments against take-home medication: Signs or symptoms of withdrawal, continued illicit drug use, the absence of laboratory evidence of methadone in urine samples, potential complications from concurrent disorders, ongoing criminal behavior, and an unstable home environment.
- Have the status of every patient provided with take-home medication reviewed by a physician at least every 90 days (or more frequently if clinically indicated) for as long as the patient is granted this privilege, and have staff from various disciplines review the merits and drawbacks of continuing take-home privileges.
- Use biochemical monitoring to ensure that the patient is free of illicit drug use and is consuming the methadone provided; implement other measures to help avoid diversion.
- Provide guidance to patients for securing methadone take-homes in their places of residence.

Chapter 8—Treating Multiple Substance Abuse

The reason an addict abuses one or more substances may relate to the chemical's ability to regulate a particular affect. For instance, heroin may relieve distress, whereas cocaine may relieve depression. Multiple substance abusers may develop unique drug regimens that vary throughout the day. Further, as methadone prevents heroin from modulating mood swings, the patient may initiate or accelerate other substances use to achieve the effect he or she is seeking. The interaction of other substances with methadone will vary depending on whether they are cross-tolerant with methadone or potentiate it.

Multiple substance use within the context of methadone maintenance treatment can and should be addressed by programs on-site or through referral. Assessment should be more detailed than for heroin dependence alone. To some extent, a range of treatment options to address multisubstance use in methadone maintenance patients exists, but these options are not well researched. They do, however, provide some clinical contribution beyond what we know now: that staying in methadone maintenance treatment for some critical period of time reduces the frequency and severity of other drug use. States have a crucial leadership role to play in promoting investigation, an expanded range of treatment options, and greater resource flexibility by developing new policies and recognizing the long-term benefits of such efforts.

Recommendations

- In carrying out an assessment, distinguish between other substance use, abuse, and dependence, and determine patterns of other drug use and self-reported etiologies, including nonprescribed, nontherapeutic use, nonprescribed therapeutic use, and prescribed, therapeutic use.
- Provide a variety of services that support cessation of nonprescribed substance use as the desired goal.
- Ensure that program objectives indicate that abstinence from other substances should extend for increasing periods, progress toward long-term abstinence, and be associated with improved life functioning and well-being.
- Devise a rational treatment plan that integrates measures for treating all psychoactive agents.
- Educate patients about their vulnerabilities from cross-tolerance, drug-drug interaction and potentiation, dependency substitution, and self-medication.
- Ensure that program staff are instructed in the goals of methadone maintenance vis-à-vis alcohol and other drug use. If working in a program with on-site staff in nonmethadone treatment modalities, provide instruction and supervision to safely integrate methadone maintenance treatment principles with drug-free models.
- Ensure that treatment options include a balance of intensified support and intensified structure in response to multisubstance use.
- Ensure that treatment options are extensive, are coordinated, and provide a continuum of care across the boundaries of physical sites and programs.
- Develop demonstration and research projects on inpatient detoxification from other drug dependencies with continuity of methadone dose.

Chapter 9—Methadone Maintenance During Pregnancy

Since the early 1970s, methadone maintenance has been recommended for narcotic dependency in pregnancy. In addition to the benefits provided by methadone maintenance treatment described in these guidelines, the use of methadone as a maintenance therapy for the pregnant woman provides the additional advantages of preventing erratic maternal opioid drug levels and protecting the fetus from repeated episodes of withdrawal. A comprehensive MMTP that includes prenatal care can reduce the incidence of obstetrical and fetal complications, in utero growth retardation, and neonatal morbidity and mortality. Additionally, maternal nutrition is usually improved, and exposure to HIV through ongoing needle use can be reduced. Comprehensive services also enable women to engage in social-psychological rehabilitation and prepare for the birth of the child.

However, methadone maintenance treatment during pregnancy is not without controversy, especially with regard to medical withdrawal, appropriate dose levels, and severity of neonatal abstinence syndrome. Perinatal and developmental outcomes of infants exposed to methadone in utero have also been areas of concern.

It is essential that the use of methadone maintenance during pregnancy be viewed within an appropriate context. Methadone is a licit drug used to treat a chronic relapsing disease and, as with any treatment drug, the risk-benefit ratio must be considered. When methadone maintenance treatment is provided for pregnant drug-dependent women within a comprehensive treatment program that addresses the medical, obstetrical, psychosocial, and addiction issues, maternal and infant morbidity and mortality are reduced and the developmental and cognitive functioning of the progeny is not impaired.

Recommendations

- Base the diagnosis of opioid addiction in the pregnant opioid-dependent woman on the same factors (e.g., medical and substance abuse history, psychosocial history, physical examination, urine toxicologies, signs and symptoms of withdrawal, etc.) that are used in diagnosing opioid addiction in nonpregnant opioid-dependent women, making sure to avoid the use of narcotic antagonists.
- Provide methadone maintenance for pregnant women within a comprehensive treatment program that addresses medical, prenatal, obstetrical, psychosocial, and addiction issues.
- When withdrawal from methadone is the selected option, conduct it under the supervision of a physician experienced in perinatal addiction, ideally in a perinatal unit equipped with fetal monitoring equipment; withdrawal *should not be* initiated before 14 weeks gestation *or* after the 32nd week of pregnancy; always avoid symptoms of withdrawal during pregnancy.
- Initially maintain women on their prepregnancy methadone dose; it is advisable to admit nonmaintained pregnant women to a hospital (for an average of 3 days) to evaluate their prenatal health status, evaluate fetal growth, document physiologic dependence, and initiate methadone maintenance.
- Monitor pregnant women and individualize their dosages as needed.
- Elevate the oral dose of methadone if needed during the later stages of pregnancy to maintain the same plasma level and avoid withdrawal.
- Delay the administration of methadone to objectively intoxicated patients until diminution of intoxification symptoms can be documented, or readmit such patients to observe them for withdrawal symptoms while augmenting their daily dose in a controlled, observable fashion.
- Provide access to HIV testing and aggressive HIV counseling and educational efforts in conjunction with narcotic abstinence support to decrease the risks of HIV infection among pregnant women, their partners, and their offspring.
- Use an abstinence scoring system to monitor passively addicted neonates in a comprehensive and objective way to assess the onset, progression, diminution of symptoms of abstinence, and to monitor effectiveness of treatment agents.
- Provide appropriate interventions, including education strategies and parent support groups, to improve the mother-infant interaction and lessen the behavioral consequences of poor mother-infant bonding.
- Breast-feeding may be encouraged during methadone maintenance treatment. However, if the patient is HIV positive or using multiple substances, breast-feeding is contraindicated.

Chapter 10— HIV and Other Infectious Diseases

HIV infection has changed the medical face of injecting drug use. Patients, particularly in high HIV prevalence areas, are sicker and in need of more intensive medical and psychosocial intervention. Many of the previously known sequelae of injecting drug use (TB, hepatitis B) are exacerbated by HIV infection.

To reckon with the problem of HIV infection in IDUs, a two-pronged approach with both prevention and intervention strategies should be used. The AIDS epidemic is first and foremost a public health issue. Drug users and their heterosexual sex partners are the two fastest growing risk groups for AIDS and, therefore, HIV infection. This fact has prompted the U.S. Public Health Service to target centers that treat IDUs, MMTPs in particular, as facilities where ready access to HIV education, counseling, and testing must be made available.

From both the public health and the substance abuse treatment standpoints, methadone maintenance is an excellent treatment modality for chronic IV opiate abusers. Numerous studies have demonstrated methadone's unique ability to retain patients (especially new patients) in treatment, as well as to significantly reduce injecting drug use, provided that adequate doses are used and competent ancillary counseling services are offered. Length of time in treatment has consistently been demonstrated to predict treatment outcome. Finally, studies have shown that HIV seroprevalence is much lower among patients who have been on long-term methadone maintenance and entered treatment prior to the onset of increasing seroprevalence within the local addict population.

Although this chapter focuses on the importance of providing HIV counseling and testing to all patients in MMTPs, it does not negate the importance of screening for other infectious diseases that are more prevalent in the addicted population than in the general public. Federal regulations already mandate tuberculin skin testing and a serologic test for syphilis for all patients upon admission to an MMTP. Screening for other infectious diseases, including viral hepatitides and STDs, is also reviewed. While screening is important and the concept of "one-stop shopping" might recommend on-site screening and followup evaluation and treatment, these are often not logistically or financially feasible in an MMTP. Where only minimal medical or public health services are available on-site, it is crucial that linkages are made with medical and public health services in the community to effect the necessary medical screening and followup.

Recommendations

- Educate all staff about HIV infection, including risk-reduction guidelines, the importance and implications of HIV counseling and testing, and infection control guidelines.
- Provide all patients entering an MMTP with HIV education, including information on modes of transmission, assessment of risk status, prevention and risk reduction guidelines, and the importance of HIV counseling and testing in prevention and intervention.
- Routinely offer HIV counseling and testing (both on-site and off-site by referral) to all patients in MMTPs and their sex and needle-sharing partners.
- Obtain informed consent from patients for HIV counseling and testing prior to testing. Adhere strictly to Federal confidentiality guidelines.
- Train and certify counseling and testing personnel to do pretest and posttest counseling.
- Have mental health professionals readily available to manage patients' potential negative reactions to HIV test results.
- Ensure that at least one identified staff person is familiar with medical and public health services that provide HIV assessment, early intervention, and treatment in the patients' geographic area, and refer patients appropriately.
- Encourage patients who are HIV positive to notify their sex and needle-sharing partners of their positive status. In some States, there may be a legal mandate for HIV-positive persons to do so.
- Provide TB counseling, screening, and treatment.
- Screen new MMPT staff for TB, and test all staff for TB annually.
- Provide screening for viral hepatitides and STDs, and ensure that any necessary medical followup occurs either on-site or through referral to community medical services.
- Provide hepatitis B vaccine to all staff considered to be at risk for exposure to HBV.

Chapter 11— Treatment Duration and Patient Retention

Duration of treatment refers to the continuation of methadone maintenance treatment. Decisions concerning duration of treatment are made by MMTP physicians, other staff, and the patient. Such clinical decisions should be based on accumulated data and medical experience, not on regulatory fiat or general policy.

In thinking about the duration of methadone maintenance treatment and its implications for patients and programs, it is important to keep in mind that recovery from narcotics addiction, both short-term (less than 6 months) and long-term (greater than 6 months), in the new DSM-IV classification is dependent on cessation of illicit use of opiates, not on the presence or absence of pharmacotherapy.

Retention in treatment refers to the patient's ability and willingness to remain in treatment over time and is influenced by a combination of patient and program characteristics. Retention is the essential element that produces optimal duration in treatment.

Retention in treatment should be considered to be the product of a continuing therapeutic relationship between recovering patients and their clinics. In addition, decisions on continuing pharmacotherapy with methadone should be made as part of the ongoing process of assessing the efficacy of specific types of treatment. Ideally, programs should be funded not only to treat patients who are receiving methadone but also those who have undergone dose reduction-elimination and are followed in a zero-dose treatment mode. Patients should always be encouraged to remain in continuing treatment; pharmacotherapy should be reinstituted if and when a relapse has occurred, is feared, or is predicted. Patients who have dropped out of treatment and are not receiving pharmacotherapy should be promptly readmitted to the program for treatment if necessary. Feelings of shame, disappointment, and relapse-related guilt, especially for a well-rehabilitated patient who has a close relationship with staff, may impair the patients' willingness and ability to seek reentry to treatment. Therefore, all obstacles to reentry should be minimized.

Recommendations

- Continue treatment as long as the patient continues to benefit from treatment, wishes to remain in treatment, remains at risk of relapse to heroin or other drug use, and suffers no significant adverse effects from continued methadone maintenance treatment, and as long as continued treatment is indicated in the professional judgement of the physician; in short, consider indefinite treatment appropriate for many patients who fit the criteria for chronic, intractable heroin addiction.
- Process patients quickly and reassure them that they will receive their initial dose of methadone on the day of application if they meet admission criteria.
- View patient retention as a major objective of treatment.

Recommendations for improving patient retention include the following:

- Make the clinic accessible; geographic decentralization is needed in those areas where the addicted population covers wide areas.
- Render treatment in the way that is least disruptive to travel, work, and educational activities, use of supportive services, and family and social services.
- Determine hours on the basis of patient needs.
- Provide affordable treatment to all who need it.
- Ensure that patients have ready access to staff, particularly to the primary counselor.
- Ensure that staff are adequately trained and are sensitive to gender- and culture- specific issues.
- Provide high-quality services.
- Offer a holistic and complete service continuum.
- Ensure that patients receive adequate doses of methadone based on individual patient needs.
- Provide a safe haven, and treat patients with dignity, respect, and compassion.

Chapter 12—The Community Effort: MMTPs as Full Community Members

Despite more than 25 years of research and practical experience in methadone maintenance treatment of opioid addicts, the public lacks knowledge of the scientific efficacy of methadone maintenance treatment. Misconceptions persist about the nature of narcotics addiction and the critical impact of methadone maintenance in mediating this problem. Although methadone maintenance treatment is associated with substantial improvements in public health and employment and a reduction in HIV risk and criminal behavior, these benefits are often overshadowed by concerns about patient loitering and drug sales that may occur in the vicinity of some large outpatient MMTPs. Residential and commercial sectors usually view clinics as threats to property value or economic prosperity or both. Further, negative community and political reaction is frequently based on strong ethical beliefs about drug addiction. While community members may be highly supportive of the concept of drug treatment, methadone is viewed as a "chemical crutch" or as the substitution of one addiction for another. Consequently, methadone maintenance patients are not considered distinct from street addicts in the mind of the community.

Misinformation about the methadone maintenance treatment modality has endured despite the field's longstanding efforts to educate legislative, health, and community leaders. Opponents of MMTPs have used protest, zoning loopholes, and negative media coverage to prevent facilities from opening or expanding. Political support has ebbed and flowed since the 1970s, remaining inconsistent and unreliable. While it varies from locale to locale, in general community response to siting and expanding methadone maintenance treatment clinics throughout the nation has been unreceptive. This resistance, in addition to threats to existing sites, keeps MMTP administrators mired in unproductive community conflicts.

By drawing from the experience of the mental health community and the drug-free residential treatment sector, the methadone maintenance treatment field has moved significantly toward adopting models and practices in community education and contacts. This work has brought many programs into the mainstream of community service and membership (and has allowed some programs to gain substantial acceptance). The chapter contains a portrait of useful elements, providing a broad perspective on developing successful community education and relations practices.

Recommendations

- Consider community need and impact in siting programs.
- Ensure that the clinic's physical appearance is clean and orderly and that the physical setting does not impede pedestrian flow.
- Identify community leaders (representatives of the district within which the clinic is situated, as well as those districts served), and establish interpersonal contact, liaison, education, and/or proactive association with the following people:
  - Publicly elected representatives
  - Local health, substance abuse, social, and/or human service agency directors
  - Business leaders
  - Community and health planning agency directors
  - Grassroots community organization leaders
  - Local police and law enforcement officials
  - Religious and spiritual leaders
- Develop and support a community relations plan specific to the configuration and needs of the program within its community.
  - Establish a liaison with community representatives to share information about the program and community and mutual issues.
  - Identify program personnel who will function as community relations coordinators, and define the goals and procedures of the community relations plan.
  - Serve as a community resource on substance abuse and related health and social issues.
  - Initiate mechanisms to hear community concerns about methadone maintenance treatment and the program's presence in the community.
  - Develop program policies and procedures to effectively address or resolve community problems (including patient loitering and methadone diversion), and ensure that program operations do not adversely affect community life.
- Document community relations efforts and community contacts, evaluate these efforts and contacts over time, and address outstanding problems or deficiencies.

Epilogue—A Personal Retrospective and Prospective Viewpoint

The epilogue provides a historical overview of the development of methadone as a successful treatment for heroin addiction, the growth of methadone maintenance treatment programs, and the present controversy and problems connected with the modality. The chapter also summarizes research initiatives from 1964 to the present; the information is presented from the perspective of a researcher who played a major role in developing methadone maintenance as a viable, legitimate treatment modality.

The author discusses the greatest needs for the future of methadone maintenance treatment. These include the needs to change general public attitudes and attitudes of policymakers with respect to this treatment; to increase funding for treatment and related research; to have adequate staff both in numbers and training; and to develop comprehensive programs, including on-site medical and psychiatric care.

Introduction

The topics and the authors for these guidelines were selected with considerable care, with input from Federal and State agencies. They were written to provide a basis for making responsible treatment decisions and crafting sound public policy when determining admissions policies, deciding on proper maintenance dosages, implementing urinalysis testing programs, establishing responsible take-home policies, implementing screening practices for HIV and other infectious diseases, determining duration of treatment and seeking to improve retention of patients in treatment, treating multiple substance abuse, caring for the pregnant patient, trying to create positive community relations, and preparing for the future. In addition, because most people who work in the methadone maintenance treatment system unfortunately do not know of the modality's extensive history, the history chapter was incorporated into these guidelines.

These topics were selected because they represent the most challenging issues to State policy officials and methadone maintenance treatment providers. At present, there are no existing nationally recognized performance-based outcome standards. The FDA and SMAs have used process-review criteria as the principal method of ensuring that programs comply with minimum standards of care. About 750 outpatient methadone maintenance programs operate in 40 States and territories, treating approximately 115,000 patients on any given day.

Some of these States have promulgated regulations that are, at times, in conflict with sound medical treatment practices. To illustrate, some States and their respective treatment providers prohibit take-home medication, while others limit the patient's length of time in treatment. Some programs improperly withdraw pregnant methadone-maintained patients only because the patient is pregnant. If a patient were to embark on a cross-country trip, that individual would receive varying degrees of medical care depending on which program or State he or she happened to be in at any point. This traveling patient might find himself or herself in a "low dose" State or a State that ties the amount of take-home methadone medication to the dosage level. Treatment providers and policy officials should be careful to avoid dysfunctional practices in treating opioid-dependent individuals if they want treatment to be effective.

It is hoped that the content of these guidelines will help individual States and programs meet the challenges of the 1990s and beyond. These challenges can only be surmounted through the spirit of mutual respect between patients, treatment providers, and regulatory officials throughout the system. Methadone maintenance treatment continues to be one of the most valuable interventions that we have in treating chronic narcotic addiction. We are obligated to provide the best care possible to the patients and their families who have placed their trust in our work.

Chapter 1—Overview: Current Treatment Realities and Future Trends

Mark W. Parrino, M.P.A.

Despite its well-documented success in treating chronic narcotic addiction for more than 25 years, methadone maintenance treatment has barely survived years of inadequate funding and negative public perception. Unfortunately, the biochemical and psychological underpinnings of narcotic addiction continue to be misunderstood, and replacement medications are still viewed with suspicion.

Dr. Vincent Dole has described the function of methadone maintenance as follows:

> The treatment is corrective, normalizing neurological and endocrinologic processes in patients whose endogenous ligand-receptor function has been deranged by long-term use of powerful narcotic drugs. Why some persons who are exposed to narcotics are more susceptible than others to this derangement and whether long-term addicts can recover normal function without maintenance therapy are questions for the future. At present, the most that can be said is that there seems to be a specific neurological basis for the compulsive use of heroin by addicts and that methadone taken in optimal doses can correct the disorder. (1988, p. 3025)

The recently published GAO report on methadone maintenance indicated that "Hercin addiction is widespread in the United States. NIDA estimates that there are approximately 500,000 heroin addicts in the United States. Treatment experts believe that heroin addiction is a chronic and relapsing disease that addicts will battle the rest of their lives" (1990, p. 8). At present, there are approximately 115,000 patients being treated with methadone maintenance in about 750 outpatient MMTPs in 40 States and territories.

An effective MMTP must be flexible in structure and properly funded if it is expected to respond to changing patient needs and fulfill public expectations. It is unfortunate that several States have adopted a policy of expanding treatment availability by placing patients into already overcrowded treatment facilities. Ten States do not have outpatient MMTPs: Arkansas, Idaho, Maine, Mississippi, Montana, New Hampshire, North Dakota, South Dakota, Vermont, and West Virginia. It is hoped that these States will use these guidelines to develop good quality methadone maintenance treatment programs, should their residents need access to such care.

The Early Rationale for Methadone Maintenance Treatment

Methadone maintenance was initially developed as an inexpensive therapeutic treatment for long-term heroin addiction. Drs. Vincent Dole, Marie Nyswander, and Mary Jeanne Kreek pioneered the use of methadone maintenance against the backdrop of rampant heroin addiction and the social turbulence of the 1960s. It was a time of increasing heroin addiction, resulting in the spread of contagious serum hepatitis and increasing overdoses in emergency rooms. An effective pharmacologic intervention had to meet stringent conditions to successfully treat narcotic addiction, as underscored by Dole, Nyswander, and Kreek:

> It must eliminate the euphoric appeal of heroin and the abstinence symptoms that draw addicts back to drug use; it must be sufficiently free from toxic dysphoric effects that patients will continue with treatment; it must be orally effective, long-acting, medically safe, and compatible with normal performance at work and at school and with responsible behavior in society. (1966, p. 304)

Years of pernicious narcotic abuse could be effectively treated by prescribing a proper daily methadone dose and providing medical care, counseling, and case management in a supportive environment. Methadone maintenance programs were more hospitable places than septic shooting galleries and crowded prison cells.

The early support for methadone maintenance treatment was rooted in the powerful correlation between untreated addicts and active criminal behavior. A retrospective study of methadone maintenance treatment admissions and drug-related arrests conducted in New York City by Dole, Des Jarlais, and Joseph (1981) showed that approximately 20,000 heroin addicts were admitted into methadone maintenance treatment between January 1, 1971, and December 31, 1973. Drug arrests decreased by 24,000, and reported cases of serum hepatitis decreased by 1,500 during the same 2-year period.

Methadone maintenance has continually demonstrated impressive results, reducing heroin use and criminal activities in over 80 percent of maintained patients. These data have been corroborated throughout the exhaustively researched history of methadone maintenance treatment, beginning with the long-term outcome study written by Dole and Joseph in 1978:

> At the time of follow-up rating, with an average time of 72 months in the program, the incidence of serious illicit opiate use had fallen from the pretreatment level of 100 percent to 1.0 percent. The arrest rate for all causes had fallen from 90 per 100 man years for the period of addiction prior to treatment to 5 per 100 man years during the years preceding the follow-up rating. (p. 183)

Chapter 2, "Historical Perspectives and Public Health Issues," was incorporated into these guidelines to provide all readers with the early rationale for this treatment modality.

Retention of Patients in Treatment

One of the great strengths of methadone maintenance treatment has been its ability to retain patients in treatment. Independent research studies have continually indicated that the physical and emotional status of patients who remained in treatment improved. Dr. Mary Jeanne Kreek, citing her research, writes that "The most important medical consequence of chronic methadone maintenance treatment, in fact, is the marked improvement in general health and nutritional status observed in patients, as compared with their status at the time of admission to treatment" (1983, p. 474).

The most current research findings supporting patient retention documented a relapse to IV heroin use in 82.1 percent of the patients who ended treatment. This relapse occurred within the first 12 months of being discharged from treatment (Ball et al. 1988). These findings should be carefully evaluated by State and local policy officials, practitioners, and funding sources who believe in restricting the patient's length of time in treatment. A number of States limit the amount of time a patient can remain in methadone maintenance treatment to 1- and 2-year periods, while others link a decision on providing take-home medication to the patient's dosage level. It is important to excerpt a portion from the concluding commentary of the article by Dole and Joseph (1978):

> In retrospect, it is surprising to see how much of the administrative policy governing the treatment of narcotics addicts has been based upon theoretical opinions, political pressures and wishful thinking, rather than experience. Regardless of whether narcotics addiction is a disease or a sin—or both—the practical reality is that most addicts with a long pretreatment history of heroin use will relapse after maintenance treatment is discontinued. To expect a limited period of maintenance to produce a high rate of permanent abstinence in this population is unrealistic. (p. 189)

Recent Critical Evaluations of Methadone Maintenance Treatment

The existing treatment system must improve if it is expected to treat heroin addiction, given the current realities of increasing patient morbidity and multiple substance abuse. This issue is underscored in chapter 10, "HIV and Other Infectious Diseases": "HIV infection has changed the medical face of injecting drug use. Patients, particularly in high HIV prevalence areas, are sicker and in need of more intensive medical and psychosocial interventions." Methadone maintenance treatment programs should offer comprehensive medical and counseling services on-site to respond to the immediate needs of the present patient population and develop an effectively managed network of ancillary referral services. The MMTPs of the 1970s were treating patients with comparatively less complex illnesses that responded to less costly interventions. For many communities, the era of inexpensive

outpatient methadone maintenance treatment ended with the appearance of HIV-spectrum disease and multidrug-resistant TB, and an increased incidence of STDs.

Two recently published evaluations of methadone maintenance treatment have had a profound impact on current policies and treatment practices. The GAO report on methadone maintenance was published during March 1990 in response to a request from Congressman Charles Rangel, Chairman of the House Select Committee on Narcotic Abuse and Control. The report cited several significant findings:

> The Federal government's two primary agencies for researching alcohol and substance abuse issues, respectively, have concluded that methadone is the most effective method available for treating heroin addiction.... In practice, however, the continued use of heroin that GAO found among patients in 24 methadone maintenance treatment programs indicated that many programs are not effectively treating heroin addiction. The use of heroin by patients in treatment for more than 6 months ranged from 1 percent at one program to 47 percent at two others. (p. 3)

The different treatment outcomes cited in the GAO study are directly related to the patients' maintenance dosage levels. These guidelines and chapter 5, "Principles of Methadone Dose Determination," were written with these findings in mind. It is unfortunate that some States and many MMTPs persist in supporting the use of subtherapeutic maintenance doses. The proper methadone dosage is the one that prevents ongoing heroin use. As chapter 5 indicates, "The determination of dose is based on an individualized clinical process using the best professional judgment of an experienced physician with expertise in the field of addiction medicine and especially the methadone maintenance treatment modality." A cardiologist does not treat heart disease by prescribing subtherapeutic doses of digoxin. Methadone maintenance treatment practitioners should not attempt to treat chronic narcotic addiction by prescribing ineffective methadone dosages. Individual State Methadone Authorities and treatment providers should critically evaluate the efficacy of their respective dosage guidelines and practices. There is no benefit to limiting an individual's daily dosage in the presence of continued substance abuse, especially in the age of HIV-spectrum disease.

A second critical GAO finding was "that policies, goals, and practices varied greatly among the 24 methadone maintenance treatment programs.... There are no Federal treatment effectiveness standards for treatment programs. Instead, Federal regulations are process-oriented in that they establish administrative requirements for programs" (p. 3).

The concept of developing standardized, objective methods for assessing drug treatment outcome and the success of treatment programs was developed in the Final Report of the White House Conference for a Drug Free America, published in June 1988. The report noted that:

> It is much more difficult to determine whether the outcome for a particular modality should be considered "successful." Measuring the success of a treatment program is complicated because drug addiction is a chronic disorder that may require numerous treatment episodes, and relapse can be one step back on the road to long-term recovery. Despite the difficulties, standardized, objective measures that recognize the differences inherent in each type of treatment modality must be developed.... Criteria that should be considered in developing the measures included program characteristics such as location and length of treatment, and client characteristics such as history of addiction, prior exposure to treatment, psychiatric illness, criminality, family relationships, and employment history or education. (p. 74)

NIDA has taken on the challenge of developing such performance-based outcome measures by conducting a feasibility study—the Methadone Treatment Quality Assurance System (MTQAS). This system, if found to be a reliable and valid measure, would evaluate the success of treatment interventions by focusing on decreased heroin and other illicit drug use, improved physical and emotional health, decreased antisocial activities, and improved social functioning.

It has become clear to many policy officials that the existing process-oriented evaluation models jointly promulgated by FDA and NIDA and by individual SMAs do not effectively measure the quality or outcome of treatment. An MMTP can be in compliance with urinalysis collection and evaluation standards and still have patients who are actively using heroin and other illicit drugs. It remains to be seen if the newly tested performance-based model can either replace the existing process-oriented review criteria or work in conjunction with more balanced Federal regulations. The 1990s will be an era of cost containment and increasing program accountability. This new evaluation process can have a

positive impact on the treatment system only if it is implemented in tandem with improved funding to meet increased expectations for addressing the primary medical care and public health needs of patients. The concept of doing "more with less" cannot work in treating narcotics addiction among the current patient population.

The MMTP is coming under increasing scrutiny as a unit of study for testing such outcome measures. Drs. Thomas and Aguillaume make a critical observation:

> The vast majority of research into heroin dependency and methadone treatment over the past two decades can be broadly categorized as concerned with either the biomedical effects of addiction and maintenance or with the social and economic impact of drug and therapy.... Seldom is this research action-oriented. Most of it is not specifically aimed at introducing policies for drug treatment or at shaping or altering existing policies. (1985, p. 741)

Methadone maintenance treatment research has become more action-oriented, especially as a result of the work of Dr. John Ball and Dr. Thomas McLellan and their respective associates. Dr. Ball and coworkers conducted a 3-year field study under a NIDA grant, evaluating six methadone maintenance programs in Baltimore, Philadelphia, and New York. Although this study had different motivating factors than the GAO report on methadone maintenance treatment, some significant findings are in agreement. The GAO report stated that "There is no typical methadone maintenance treatment program." Dr. Ball and coworkers' study arrived at a similar conclusion: "Marked differences in the effectiveness of various programs were observed: Current IV use varied from less than 10 percent to over 57 percent of patients in particular treatment programs" (1988). They went on to report a powerful conclusion:

> It is a major finding that some methadone programs are markedly more effective than others in reducing IV drug use and needle sharing among their patients because these differences in treatment outcome are related to definite program variables. The more effective programs have high patient retention rates, high rates of scheduled attendance, a close, consistent and enduring relationship between staff and patients, and year-to-year stability of treatment staff. Conversely, the less effective programs are characterized by poor patient attendance, inadequate methadone medication, and high rates of staff turnover. Effective and ineffective programs, however, did not differ with regard to patient characteristics. (1988, p. 223)

The importance of these findings cannot be overstated as the treatment system is expected to meet the challenge of treating a more complex illness. Federal and State policy officials and treatment practitioners should come to terms with the need to provide adequate funding to secure good treatment outcomes. The effective programs in Dr. Ball's study were well managed, properly funded entities with well-trained and supportive staff. These programs prescribed and administered therapeutic methadone dosages and provided comprehensive counseling and medical services. The remarkable finding does not lie in the conclusion of any one study but in the fact that positive outcomes are directly related to an investment in comprehensive treatment resources. A program is only as effective as its staff, management, and year-to-year organizational stability.

Drs. McLellan, Arndt, Metzger, Woody, and O'Brien (in press) have been evaluating the impact of providing different levels of care in methadone maintenance treatment on patient outcomes. Their research findings support using comprehensive treatment approaches to rehabilitate chronic heroin addicts. The study states, "It should be noted that these findings are quite consistent with a growing body of work from Hubbard, Joe and Simpson, Ball and others...showing that those substance abuse patients who receive the most services during treatment have the best outcomes; and that those substance abuse treatment programs that provide the most services to their clients have the best programmatic results" (p.10).

The study employed random assignment of newly admitted patients from Philadelphia into three groups within the same treatment program. Three levels of methadone maintenance treatment services were prospectively evaluated over a 6-month period:

- **Minimum Methadone Services**—Minimum daily dose of 60 mg but no regular counseling and no extra services
- **Standard Methadone Services**—Minimum daily dose of 60 mg plus regular counseling but no extra services
- **Enhanced Methadone Services**—Minimum daily dose of 60 mg plus regular counseling, on-site medical and psychiatric care, family therapy, and employment counseling

Not surprisingly, the best outcome was observed in the patients who participated in the enhanced methadone maintenance treatment program.

Changing Patient Characteristics and the Need for Comprehensive Care

The characteristics of people entering methadone maintenance treatment have changed dramatically since the mid-1980s. When methadone maintenance treatment first began, most addicts used heroin as their primary drug of abuse. Increasingly, patients enter treatment with significant multiple addictions, particularly to alcohol, cocaine, and antianxiety agents. Chapter 8 provides a comprehensive set of guidelines for treating multiple substance abuse in methadone maintenance treatment. This chapter indicates that "The intensity of treatment should be based on the needs of the patient, which depends on the magnitude of change that a patient has to make in order to achieve and maintain abstinence from drugs." Programs should intensify treatment services in response to the patient's multiple substance abuse, as opposed to prematurely discharging the patient without the benefit of more focused interventions.

From the late 1960s through the 1970s, the significant medical concern in methadone maintenance treatment was contagious serum hepatitis. In recent years, patient morbidity has increased as the incidence of HIV-spectrum disease and multidrug-resistant TB has increased. Patients are at greater risk for STDs, pneumonia, and a host of other debilitating diseases that require more intense medical attention at the program site. Methadone maintenance programs are evolving into critically needed resources in preserving and protecting the public's health. Increasingly, MMTPs may be administering antiretroviral and antitubercular medications at or through the methadone maintenance program site.

The staffing complement of existing programs is usually not adequate to respond to these needs. Treatment programs should become more staff intensive, especially in the counseling and medical departments. This writer agrees with Dr. Vincent Dole's assertions in the book *Addicts Who Survived: An Oral History of Narcotic Use in America, 1923-1965:*

> The problem was one of rehabilitating people with a very complicated mixture of social problems on top of a specific medical problem, and that [practitioners] ought to tailor their programs to the kind of problem they were dealing with. The strength of the early programs as designed by Marie Nyswander was in their sensitivity to individual human problems. The stupidity of thinking that just giving methadone will solve a complicated problem seems to me beyond comprehension. (1989, p. 338)

The psychosocial and medical problems have become even more complicated in the age of HIV infection. Policy officials need to encourage program flexibility in responding to the specific requirements of the patients, keeping in mind the findings of Dr. Ball and other researchers.

Medical, case management, and counseling caseload numbers should be adjusted to the specific needs of an individual methadone maintenance program's patient population. The MMTP's manager, in conjunction with treatment personnel, should develop a comprehensive patient profile, which should be updated annually, and include the following elements:

- The number of suspected or known AIDS cases
- The number of estimated or known HIV-positive patients or patients infected with TB or STDs
- The trends in alcohol, opiate, cocaine, and other forms of substance abuse, including routes of administration
- The number of vocational counseling and job referral candidates
- The number of patients in need of specialized medical care
- The number of pregnant women
- A comprehensive morbidity index for all patients in treatment

Once this assessment has been completed, the manager can begin to match the appropriate mix of personnel to specific patient characteristics and determine the range of services that can be provided with the available funds. Medical practitioners and clinicians should not be placed in the role of overwhelmed caretakers. Positive and sustained outcomes can only be achieved in a therapeutic environment with available and supportive caregivers. It is practically impossible to provide good quality care to treat a complex illness if the program environment is chaotic, with poor management and overburdened treatment providers. No one should expect a favorable outcome in such cases, and as research indicates, it does not occur. Caseloads should be configured to provide better access to HIV counseling and intensive clinical support for treating active alcohol and drug-using patients. The present patient population requires access to specialized treatment services at or near the program site. The importance of such "primary medical care services" is discussed in chapter 10, "HIV and Other Infectious Diseases."

Patient peer support groups should also be encouraged to meet in methadone maintenance programs, adapting the structure of the self-help models that are

discussed in chapter 3, "Review of Clinical Issues." The chapter notes that "...the integration of self-help programs into methadone maintenance treatment is one of the most exciting recent developments. However, it is important that patients be encouraged rather than required to participate because the programs are akin to two disparate cultures beginning to come to terms with each other, and this accommodation process cannot thrive under mandates and constraints." It is inevitable that methadone maintenance treatment will work in cooperation with self-help models since the patients require the added strength of peer support groups as part of their progress in treatment. Increasingly, methadone maintenance will gain wider acceptance in the recovery communities.

Efficacy of Treatment: Public Misunderstanding and Proposed Solutions

Four issues have overshadowed the documented success of methadone maintenance treatment:

- Patient loitering
- Methadone diversion
- Relative lack of advocacy on behalf of MMTPs
- Lack of public understanding and awareness

Patient Loitering

Patient loitering is a critical matter that should be taken seriously by program management and personnel. Methadone maintenance programs can continue to exist by remaining as invisible as possible to the surrounding community, while simultaneously building a network of neighborhood contacts through effective public relations. This point is underscored in chapter 12: "Proactive work with communities, particularly with community leaders (political and otherwise) is the natural and practical course. This approach establishes the methadone maintenance treatment program as an integral community member and offers an opportunity to prevent and resolve problems that could threaten the program's relationship with its community." A treatment program can typically prevent loitering by having well-established policies that are integral to the treatment process and maintained by a well-managed and stable security complement. At times, patient loitering is the result of a large number of patients being treated at one site or the clustering of many programs within a small geographic radius. Unfortunately, a small percentage of patients are responsible for this problem.

Methadone Diversion

Although it may be argued that illicit methadone sales are related in part to the lack of available treatment, patients who sell their take-home medication typically sell it to drug users who either do not need or do not want methadone maintenance treatment or who are unable to meet the established admission criteria. Treatment programs should take seriously the sale or diversion of medication. The program should develop and implement clear policies about these issues and take the appropriate action if patients are not using their medication as prescribed. If treatment providers fail to address this matter and continue to give take-home medication to unstable or drug-using patients, regulatory officials may implement greater restrictions, which will impede the progress of more responsible and successful patients. Most methadone-maintained patients use their take-home medication as prescribed and suffer as a result of those who engage in illicit transactions. Chapter 7 provides practical suggestions for responsible take-home medication practices.

Mandated daily patient visits should not be implemented across the board as some policy officials have suggested. Thousands of successfully recovering former heroin addicts would be compelled to leave methadone maintenance treatment if they were denied take-home medication despite individual progress in treatment. It is important to note that some patients will require the structure of daily program visits because they will not be able to responsibly care for their take-home medication.

Relative Lack of Advocacy on Behalf of MMTPs

A significant number of MMTPs do not have the capacity to treat all heroin addicts who are interested in receiving such intensive care. While methadone as an effective medication is critical to reversing the debilitating effects of years of untreated narcotic addiction, it is only one component of a holistic treatment effort. If policy officials want to make methadone maintenance treatment more available, then sufficient fiscal and programmatic resources should be allocated to develop such programs.

At present, there are two competing currents among public policymakers regarding expansion of methadone maintenance treatment. The first group believes that treatment programs must (1) be responsive to changing patient characteristics, (2) individually gear treatment interventions to the patient and provide more comprehensive services at the program site, (3) provide adequate medical care to treat increasing patient morbidity, (4) implement infectious disease procedures as the incidence of TB and other infectious diseases continues to increase in the IDU

population, and (5) develop health surveillance protocols for treatment personnel.

The second group of policymakers recognizes these realities but insists that the government does not have enough money to sustain comprehensive treatment services, especially at a time of State budget deficits. Some policymakers suggest that more creative management of limited resources will actually achieve better results with a sicker population. Dr. McLellan and coworkers' previously cited research does not support this point of view:

> It is clear that increasing the availability of methadone to out-of-treatment, IV opiate users is a desirable goal; and we agree that appropriate doses of methadone alone without any additional services can result in reductions in opiate use. However, the present data indicate that a public policy associated with the expansion of methadone availability may be a necessary but certainly not a sufficient medical response to the multiple problems of opiate dependence, psychiatric illness, AIDS and other infectious diseases that make this group of individuals such a public health concern. (in press).

MMTPs should engage elected officials and community leaders in developing new program sites. Treatment expansion cannot be implemented by crowding a greater number of sicker patients into the existing programs or downgrading the existing complement of services. Some Federal officials are predicting another increase in heroin use. If this prediction comes to fruition, our Nation may require new or expanded treatment facilities, which must be preceded by a well-planned public education campaign.

Lack of Public Understanding and Awareness

The methadone maintenance treatment process continues to be shrouded in misunderstanding and mystery. Many people still believe that methadone is injected. A number of patients also believe that methadone causes "bones to rot" and teeth to decay. Others believe that methadone-maintained pregnant women are creating the next generation of narcotic-dependent individuals since methadone crosses the placental barrier. These myths can only be dispelled through ongoing education.

A national public relations campaign is needed to educate the public about the value of methadone maintenance treatment before any meaningful program expansion can occur. Treatment needs to be portrayed as a concrete intervention in which the heroin addict is seen in humane terms and is progressively challenged through incremental steps in the rehabilitation process by a team of experienced professionals and successfully recovering peers. Patient advocacy groups should organize and participate in this public education through radio interviews and other media events. Methadone maintenance treatment should be characterized as improving the quality of life for the individual patient, his or her family, and society by reducing criminal behavior and enhancing socially productive lifestyles. Methadone maintenance treatment reduces general health care expenditures, contains the spread of AIDS and other infectious diseases, and frees the criminal justice system to deal with other crimes.

Methadone maintenance treatment programs should also learn to more effectively engage the community through cooperative "good neighbor" projects, open house community visits in the treatment setting, and educational forums. Methadone maintenance treatment centers need to be perceived as valuable community-based resources, instead of gathering places for the socially disenfranchised. Program personnel must actively participate in the neighborhood meetings on a regular basis. It is much harder to throw stones of disapproval at the glass house of the drug treatment program if the community is inside the front door. Attractive facilities can also engender good community public relations, in addition to serving the primary interests of recovering patients. Chapter 12, "The Community Effort," was included in these guidelines to provide practical methods of engaging in positive community education. We can only change public opinion by addressing the concerns of neighborhood residents on their ground.

Summary: Future Methadone Maintenance Treatment Initiatives

The 1990s will be critical for methadone maintenance treatment and the entire substance abuse prevention and treatment system. There will be a more sustained regulatory presence at the Federal and State levels, which will work in tandem with legislative oversight. We are entering an era of greater accountability that will see the implementation of standardized, performance-based outcome measures.

Methadone maintenance treatment providers and policy officials should determine what kind of system is needed to effectively treat a more complex illness. Methadone-related research can provide enormous guidance in determining the most effective mix of services to be offered. Historically, methadone maintenance treatment has been characterized as a cost-effective treatment intervention for retaining long-term opioid-dependent addicts. The public policy support for methadone maintenance was founded on obtaining good dollar value in reducing drug-related crime and improving the patients' well-being. Comprehensive treatment services should continue to be a good investment, resulting in a reduction in the incidence of untreated heroin addiction, the incarceration of untreated addicts committing crimes to support their pernicious dependence, and the extraordinary costs associated with treating AIDS.

The authors contributing to these guidelines have underscored the fact that we are collectively dealing with a different set of demands. Treatment personnel require enhanced training to respond to issues of serious medical illness and death, and methadone maintenance providers will be under greater pressure to offer a richer mix of comprehensive services. Peer support groups will become a permanent part of the treatment system. More medical care will be offered at the clinic site as programs create better primary health care linkages to the mainstream medical communities. Vocational referral and job placement will become more critical treatment components as outcome measures are used to evaluate treatment success and as incentives are built into third-party insurance packages. More programs will begin to address the tragic realities of intergenerational substance abuse by implementing parenting skill workshops at or through the treatment setting. Many patients in treatment need to break through the dysfunctional habits that were learned at the hands of their own parents to prevent the damage from going any further.

The euphemism of doing "more with less" should be removed from the regulatory and financing lexicons if we are to shape a more responsive and patient-driven system of care. Treatment resources can be more efficiently used as more policy-driven research indicates how to choose the best mix of personnel for treating patients at different phases of their care. The annual cost of providing these services should be realistically determined through credible planning initiatives by State officials, with direct input from methadone maintenance providers.

The challenges of this decade can only be met and overcome through the spirit of mutual respect between regulatory officials, methadone maintenance treatment providers, and patients. Patients can only do well in a therapeutic environment with access to caring and competent staff. The work of staff must be supported in action and spirit by program management. In turn, responsible program management should be supported through thoughtful Federal and State policy initiatives. The methadone maintenance treatment system should be strengthened and improved if it is to care more effectively for less healthy people.

Recommendations

- Offer comprehensive medical and counseling services on-site to respond to the immediate needs of the present patient population and develop an effectively managed network of ancillary referral services.
- Plan medical, case management, and counseling caseload numbers around the specific needs of the program's patient population.
- Configure caseloads to provide better access to HIV counseling and intensive clinical support for active alcohol- and drug-using patients.
- Encourage patient peer support and self-help groups to meet in methadone maintenance treatment programs.
- Take patient loitering seriously; prevent loitering by having well-established policies that are integral to the treatment process and are maintained by a well-managed and stable security complement.
- Educate the public about the value of methadone maintenance treatment.
- Use cooperative "good neighbor" projects, open houses, and educational forums to more effectively engage the community.
- Seek to use treatment resources more efficiently; this goal will become more achievable as policy-driven research increasingly suggests how to use the best mix of personnel in treating patients at different phases of their care.
- Develop different models of care that respond to individual patient needs during different phases of the methadone maintenance treatment experience. Newly admitted patients will require ready access to a broad range of services, while successfully stabilized patients who have been maintained on methadone for several years may require less intensive services.

References

Ball, J.C.; Lange, R.W.; Myers, C.P.; and Friedman, S.R. Reducing the risk of AIDS through methadone

maintenance treatment. *Journal of Health and Social Behavior* 29:214–226, 1988.

Dole, V.P. Addictive behavior. *Scientific American* December:138–417,1980.

Dole, V.P. Implications of methadone maintenance for theories of narcotic addiction. *Journal of the American Medical Association* 260:3025–3029, 1988.

Dole, V.P. Methadone maintenance. In: Courtwright, D.; Joseph, H.; and Des Jarlais, D. *Addicts Who Survived: An Oral History of Narcotic Use in America, 1923–1965*. Knoxville: University of Tennessee Press, 1989. pp. 331–343.

Dole, V.P.; Des Jarlais, D.J.; and Joseph, H. "Costs and Benefits of Treating Chronic Users of Heroin with Methadone Maintenance." Unpublished report, The Rockefeller University and the New York State Division of Substance Abuse Services, 1981.

Dole, V.P., and Joseph, H. Long-term outcome of patients treated with methadone maintenance. *Annals of the New York Academy of Sciences* 311:181–189, 1978.

Dole, V.P.; Nyswander, M.; and Kreek, M.J. Narcotic blockade. *Archives of Internal Medicine* 118:304–309, 1966.

General Accounting Office. *Methadone Maintenance—Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed*. GAO/HRD-90-104, Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1990.

Kreek, M.J. Health consequences associated with the use of methadone. In: Cooper, J.R.; Altman, F.; Brown, B.S.; and Czechowicz, D., eds. *Research on the Treatment of Narcotic Addiction: State of the Art*. National Institute on Drug Abuse Research Monograph 83-1201. Rockville, MD: National Institute on Drug Abuse, 1983.

McLellan, A.T.; Arndt, I.O.; Metzger, D.S.; Woody, G.E.; and O'Brien, C.P. Are psychosocial services necessary in substance abuse treatment? *Journal of the American Medical Association*, in press.

Thomas, R.I., and Aguillaume, C.J. The role of research when a biomedical issue is politicized: The regulation of methadone maintenance programs. *The Mount Sinai Journal of Medicine* 52:740–741, 1985.

White House Conference for a Drug Free America. Final Report, 1988.

Chapter 2—Historical Perspectives and Public Health Issues

Herman Joseph
Phil Appel, Ph.D.

The use of methadone maintenance to treat addiction to heroin and other opiates was developed in the mid-1960s and has become the most widely employed treatment of opiate dependence in the United States. Consistent with its origins as an intervention to curb heroin addiction, methadone maintenance treatment now has another public health role to play: helping curtail the spread of HIV among opiate-dependent IDUs.

Methadone was synthesized in Germany during World War II as an analgesic alternative to morphine. The drug was first studied in this country in 1946 at the U.S. Public Health Hospital in Lexington, Kentucky, after the war. Methadone was found to be similar to morphine in its effects but possibly longer acting. The drug could be used effectively to treat opiate withdrawal syndrome by substituting methadone for morphine and slowly tapering the dose over a period of about 7–10 days, as shown by clinical research.

Before methadone maintenance treatment was developed in 1964, methadone was used primarily in the treatment of addiction to withdraw addicts from heroin, a short-term procedure that exploits only some of methadone's potentially useful properties. Methadone maintenance treatment, on the other hand, involves administering a constant, therapeutic daily dose of methadone after an initial period of buildup or stabilization, concomitantly with medical, rehabilitation, and counseling services.

This treatment regimen, when correctly implemented and adhered to, can produce dramatic improvements in individuals who were formerly dysfunctional addicts. In clinics throughout the world, methadone maintenance treatment patients have been restored to productive lives. Many have furthered their educations, obtained training and employment, resumed or established careers and businesses, improved their physical and mental well-being, and renewed family relationships. Nevertheless, the treatment regimen remains a source of contention among substance abuse treatment providers, public officials and policymakers, the public, and the substance abuse treatment profession itself, despite more than two decades of research and evaluation that internationally document its safety and efficacy.

The next section discusses the historical background of opiate dependence in the United States and how conflicting attitudes toward opiate maintenance treatment existed prior to the development of methadone maintenance. These attitudes continue to influence policy toward the modality despite scientific evidence that it is safe and effective. The chapter concludes with a discussion of some issues of concern, such as methadone's medical safety, its role in treating opioid-dependent, pregnant women, and its role as a public health intervention to prevent the spread of HIV.

Historical Perspectives

During the past century, historical, political, and social forces shaped the nature of opiate dependency in the United States. Opiate dependency has occurred in a variety of groups at different times, suggesting that the availability of narcotics and personal biological vulnerability, as opposed to a unique set of social or personality characteristics, cause narcotic dependence. A variety of social or personality characteristics may influence the expression of an addictive disorder, but historical evidence rules against the concept of these characteristics being at the root of addiction.

To illustrate this point, older white women from the middle and upper socioeconomic classes constituted about two-thirds of those addicted to opiates (morphine sulfate and laudanum) during the late 19th century. Narcotics were widely prescribed to alleviate acute and chronic discomfort and stress, which resulted in iatrogenic addiction. There were an estimated 300,000 opiate-dependent persons in the United States by 1900. The prototype iatrogenic, white, female

addict of this particular era was the mother of playwright Eugene O'Neill, Mary Tyrone, portrayed in the autobiographical drama, "Long Day's Journey Into Night." Another group medically addicted to narcotics in the late 19th century were disabled and wounded veterans of the Civil War (Courtwright 1982; Courtwright et al. 1989).

Iatrogenic addiction among middle and upper class older white women and disabled war veterans was regarded as an unfortunate medical condition and thus elicited tolerance and empathy. Neither group presented major social problems. Doctors prescribed narcotics to these groups, and sanatoria were established for questionable "cures" of the resulting opiate addiction. However, the chronic nature of addiction was evident, as many of the patients who entered the sanatoria for the cure relapsed after discharge. In the above-mentioned play, the addictive qualities of morphine and the high relapse rate were known to Eugene O'Neill's father, which contributed to his refusal to send his wife to a sanatorium. Addicted Civil War veterans and elderly white women were dying by the end of the century, and doctors became more cautious in prescribing narcotics to their patients. Eventually the prevalence and incidence of addiction diminished in these two groups.

The arrival of waves of European immigrants at the turn of the century changed the composition of the addicted population. Impoverished young adults, crowded into tenements and ghettos, became susceptible to addiction. Use of opium, cocaine, and heroin and drug-related crime were sources of concern to social, religious, and political leaders in poor, urban communities.

In the decades after World War II, another major change in the opiate-dependent population occurred. There was a mass migration of African-Americans from rural areas and cities in the southern United States and Hispanics from Puerto Rico, the Caribbean Islands, and Central and South America to northern and western cities during this period. As European immigrants moved out of the crowded cities, Hispanics and African-Americans moved into the vacated tenements in areas with preexisting problems of narcotics addiction and trafficking. An ethnic succession of narcotics addicts occurred in these neighborhoods, with African-Americans and Hispanics replacing those of white European background (Courtwright 1982; Courtwright et al. 1989).

A corresponding change in attitudes toward addicts also occurred—from compassion and support for the iatrogenically addicted, older, white females and disabled Civil War veterans to discrimination and stigmatization of poor white, Chinese, African-American, and Hispanic addicts in the inner-city ghettos. This stigmatization of addicts and their drugs of abuse reflected class and ethnic biases within the community, and this culturally biased perspective was extended to methadone after it was introduced as a medical maintenance medication in the 1960s.

These attitudes have found expression in over eight decades of restrictive Federal legislation and local statutes beginning with the passage of the Harrison Narcotic Act of 1914 (Courtwright et al. 1989). This act was passed by Congress to fulfill U.S. obligations to uphold the international agreement of the 1912 Hague Convention to help curtail the opium trade in southeast Asia and China. Although mercantile and trade interests of the United States were also at stake, the transformation of American addicts to a white criminal underclass and a Chinese minority in the first decades of the century was used as a rationale for enacting the statute (Brecher 1972; Courtwright 1982; Courtwright et al. 1989).

The Harrison Act was not originally constructed as a prohibition law but as a measure to regulate the manufacture, distribution, and prescription of opiates, coca, and their derivatives. Manufacturers, pharmacists, and physicians had to be licensed, keep records for inspection, and pay a modest fee to the Internal Revenue Bureau of the Treasury Department. The act did not, however, deal directly with the issue of physicians prescribing narcotics to maintain addicts. It and a 1919 amendment allowed physicians to prescribe narcotics for "legitimate medical purposes" in the course "of their professional practice only," but did not define the two phrases. Because the Treasury Department's Narcotics Division took the position that addiction was not a disease and that addicts were not legitimate patients, it followed from their interpretation of the law that physicians who prescribed drugs for maintenance were not prescribing to patients in the course of their professional practices. Thus, the Treasury Department adopted an antimaintenance attitude that eventually resulted in the harassment and imprisonment of doctors who continued to treat addiction by prescribing opiates (Brecher 1972; Courtwright 1982; Courtwright et al. 1989; Gewirtz 1969).

Before the Harrison Act was passed, opiate-dispensing clinics had already been opened in Florida, in 1912, and Tennessee, in 1913. After the antimaintenance decisions of the Supreme Court in 1919[1], 13 municipalities with large populations of addicts established about 44 opiate clinics in which morphine was prescribed or

dispensed to addicts. Some clinics prescribed heroin and cocaine (Courtwright et al. 1989).

Clinics varied in their functions: Some were detoxification programs, and others adopted a maintenance policy (Brecher 1972; Cooper 1988; Courtwright 1982; Courtwright et al. 1989; Gewirtz 1969). Morphine maintenance is not an efficient procedure, however, because of morphine's short duration of action (4 to 6 hours), the increasing tolerance level requiring periodic patient dose increases, the need to inject the drug several times a day, and the persistence of incapacitating narcotic effects, such as somnolence (Courtwright et al. 1989; Joseph and Dole 1970). In the period 1912–24, long-acting narcotics such as methadone had not yet been synthesized or conceptualized, and physicians had to use the drugs of the period to address a serious health problem.

Perhaps the most famous clinics were the Department of Health clinic in New York City, where addicts were detoxified with decreasing doses of heroin and morphine, and the clinic established by Dr. Willis Butler in Shreveport, Louisiana. Dr. Butler not only detoxified patients, but also maintained the addicted citizenry on morphine, including, among others, the local sheriff's elderly, infirm mother. The Commissioner of Public Safety objected to the presence of the opiate clinic in Shreveport until he discovered that his own mother was a patient. This example illustrates an important point: The perception of who is addicted influences the attitude toward addiction (Courtwright et al. 1989).

Clinics differed in the way they were administered. Some were well run and kept accurate records, while others were haphazard in their operation; some clinics operated for profit while others were part of a public health policy. Irrespective of their clinical function, administrative status, or effectiveness, the clinics were regarded by the Treasury Department as a threat to its antimaintenance philosophy. A campaign ensued to close the clinics using legal pressure, critical inspections, and threats. By 1923, the Treasury Department succeeded in this undertaking. The last clinic to be closed was the one operated by Dr. Butler in Shreveport (Courtwright 1982; Courtwright et al. 1989).

With the closing of the opiate treatment clinics, there were no governmental programs for the treatment of addiction. Subsequently, an increase in crime associated with the acquisition of narcotics was reported in cities throughout the country. In 1929, Congress appropriated funds to establish a treatment facility, the U.S. Public Health Service Hospital in Lexington, Kentucky, which opened to patients in 1936. This institution detoxified addicts who entered voluntarily and also served as a prison hospital for convicted and sentenced addicts. The prescribed stay in the institution was about 6 months, although some patients stayed longer. While the hospital offered social, medical, psychological, and psychiatric services in addition to detoxification and had a low patient-to-staff ratio (2 to 1), the atmosphere was nevertheless prisonlike. Two major followup studies showed the program to be a failure. One study reported a relapse rate of 93 percent in 1,912 former patients over a 1-to-4.5-year followup period; a second study found a relapse rate of 97 percent in 453 former patients over followup periods of 6 months to 5 years. Because of these failure rates and the subsequent establishment of community-based programs, the hospital facility was turned over to the Bureau of Prisons in 1974 (Brecher 1972; Courtwright et al. 1989).

The increase in heroin addiction in New York City following World War II led to the establishment of Riverside Hospital for adolescent addicts. The hospital, located on North Brothers Island in the East River, had 141 beds and a professional staff of 51. A followup study by Dr. Harold Alksne in 1956 showed that of the 247 patients admitted in 1955, 86 percent had relapsed, 11 percent had died, and only eight former patients (3 percent) were abstinent. Upon further investigation, it was found that the eight patients abstinent at followup were never addicted but were arrested on narcotics charges and chose hospitalization over jail. The facility was closed in 1961 by Dr. Ray Trussell, then Commissioner of the New York City Department of Hospitals (Brecher 1972).

The narrow and punitive interpretation of the Harrison Act by the Federal Narcotics Division led to an era of restrictive narcotics regulation. Harassment, arrests, and convictions of physicians who prescribed narcotic drugs for maintenance were common enough to stand as a warning to the medical profession. Subsequently, addicts were forced to buy drugs on the black market and were subject to street violence, diseases associated with use of unsterilized needles, arrests, convictions, and incarcerations (Brecher 1972). By 1970, Congress had passed 55 antinarcotics laws, and State legislatures had supplemented Federal laws with hundreds of local statutes.

In the 1950s, trends in cities throughout the United States were becoming clear. The number of heroin addicts was increasing, as was addiction-related crime. By the 1980s, there were an estimated 500,000 narcotics users in the country, most located in the inner cities among poor, minority young men and women. While this represented a 66-percent increase

over the estimated number of addicts in the late 19th century, the per capita rate of addiction was much less than in the late 19th century because the population had more than doubled (Courtwright et al. 1989). Also, by the 1960s, the composition of the addicted population had changed from white, middle and upper class women and wounded Civil War veterans to poverty-stricken, largely nonwhite people living in the ghettos of major American cities. Addiction became not only a major medical problem but an explosive social issue (Courtwright 1982; Courtwright et al. 1989).

To allay fears of addiction-related crimes against property in the inner cities, civil commitment was instituted in California and New York State. Addicts could be committed to facilities through a voluntary procedure that included a medical examination to validate the presence of an addiction or be committed for 3 years when arrested on a misdemeanor charge as an alternative sentence to jail. The civil commitment program instituted in New York in 1966 turned out to be exceedingly expensive; it cost about $150 million per year to commit 5,800 addicts, while the positive results were minimal (Brecher 1972). The great majority of addicts absconded from aftercare programs to which they were paroled after a period of institutionalization in a State commitment facility and could not be located. A review of the California civil commitment experience showed that five out of every six addicts committed and placed on aftercare in the 1960s either relapsed, were rearrested, absconded, died, or were removed from the program by a writ of habeas corpus (Brecher 1972; Inciardi 1988; Joseph 1988; Joseph and Dole 1970; Maddux 1988).

Both the legal and medical professions in the United States were perturbed by the post-World War II rise in heroin addiction and the serious personal, social, and medical consequences of American policy. In 1956, the Joint Committee of the American Bar Association and the American Medical Association was formed to study the problem. In 1958, the committee issued its report recommending that an outpatient facility prescribing narcotics be established on a controlled experimental basis (Brecher 1972).

Other prestigious groups voiced support for the concept of an opiate maintenance clinic. The New York Academy of Medicine recommended in 1955 and again in 1963 that clinics be established in affiliation with hospitals to dispense narcotics to addicts. In 1956, the American Medical Association advocated a research project that would investigate the feasibility of dispensing narcotics within a clinic. In 1963, President Kennedy's Advisory Commission on Narcotic and Drug Abuse also recommended that research be implemented to determine the effectiveness of dispensing narcotics to addicts in outpatient clinics (Brecher 1972). After many years of punitive legislation and policy, support grew for narcotic maintenance, especially because no effective abstinence-based alternative existed to treat the large number of addicts.

The Origins of Methadone Maintenance

With the medical and legal professions calling for a reevaluation of American policies concerning the treatment of addicts, the climate was more favorable for a challenge to the Narcotics Division's antimaintenance position. By the mid- and late 1960s, heroin-related mortality was the leading cause of death for young adults between 15 and 35 in New York City. The number of serum hepatitis cases related to injection of opiates with contaminated needles was increasing. Record numbers of addicts were being arrested for drug-related crimes (e.g., possession, sales, robbery, and burglary), and overcrowded jails had no effective medical care available to ease detoxification (Inciardi 1988; Joseph and Dole 1970). By 1968, the Manhattan County Jail for Men (known as the Tombs) was wrecked by riots because of the poor living conditions, severe overcrowding, and lack of medical care for arrested addicts.

In 1962, Dr. Vincent P. Dole, a specialist in metabolism at The Rockefeller University, was appointed chair of the Narcotics Committee of the Health Research Council of New York City by Dr. Lewis Thomas. Dr. Dole received a grant from the Health Research Council to establish a research unit to investigate the feasibility of opiate maintenance after studying the scientific, public health, and social ramifications of the addiction problem in the city. In preparing for his research at The Rockefeller University he read *The Heroin Addict as a Patient* by Dr. Marie E. Nyswander, a psychiatrist who had extensive experience treating addicts. She had served as a physician at the U.S. Public Health Service Hospital in Lexington, Kentucky, treated addicts in private psychiatric practice, and established a storefront for treating addicts in East Harlem; she was also the psychiatrist for the Musicians Clinic, a program which treated addicted musicians. Dr. Nyswander was convinced addicts could be treated as patients within general medical practice. However, she was of the opinion that many would have to be maintained on narcotics in order to function, since the majority relapsed, notwithstanding detoxifications,

hospitalizations, and psychotherapy (Brecher 1972; Courtwright et al. 1989). Dr. Nyswander joined Dr. Dole's research staff in 1964. Also recruited to join the research team was a young clinical investigator, Dr. Mary Jeanne Kreek, who was completing her training in internal medicine and neuroendocrinology at the New York Hospital-Cornell Medical Center.

Maintenance with low doses of morphine was first administered to two patients who had used narcotics for at least 8 years and had extensive criminal histories related to their addictions. Both had previously attempted therapy and had detoxified several times only to relapse. Since morphine has a half-life of 4–6 hours, the patients required injections four times per day. They remained preoccupied with drugs and were apathetic and sedated from the narcotizing effects of morphine. As tolerance to the morphine developed, they required increasing amounts administered at more frequent intervals to remain comfortable.

The researchers knew that morphine, which is related to heroin, was not a good choice as an opiate maintenance medication because the patient's social functioning was impaired by morphine's narcotizing qualities. Also, the short half-life of the drug requires several injections per day and as tolerance develops, increasing amounts are needed over a short time for patients to remain comfortable. Other short-acting narcotics, such as heroin, codeine, oxycodone, and meriperidine, showed similar results (Dole 1980, 1988; Dole et al. 1966).

With short-acting narcotics eliminated as options for maintenance, the research focused on another possible maintenance drug. Methadone appeared to be orally effective and long-acting and was selected on the basis of observations of its use in withdrawing addicts from heroin and as an analgesic in the experimental treatment of pain (Dole 1980, 1988; Joseph and Dole 1970; Kreek 1973). However, in 1964 technology was not available to measure blood levels of heroin, morphine, and methadone to assess duration of action. At that time, proof of the efficacy of methadone maintenance treatment was dependent on observation and recognition by insightful researchers.

Methadone was then administered to the patients who had first been maintained on morphine. Once tolerance to a dose of 80–120 mg/day was established, it was noted that patients were able to function normally without the anxiety associated with drug craving. During the research phase of methadone maintenance treatment, the following six important findings about methadone were noted; they support a maintenance program's ability to permit otherwise intractable addicts to function normally in a socially acceptable manner (Dole 1980, 1988; Kreek 1973).

- The patients did not experience euphoric, tranquilizing, or analgesic effects. Their affect and consciousness were normal. Thus, they were able to socialize and work normally without the incapacitating properties of short-acting narcotics like morphine or heroin (Dole 1980, 1988; Dole et al. 1966; Kreek 1973).
- At a methadone dose between 80 and 120 mg/day, tolerance to the narcotic effects of all opiate-class drugs (e.g., morphine, heroin, Demerol, opium) was held at a level high enough to block their euphoric and tranquilizing effects if the patient administered them by injection or by smoking.
- There was no change in tolerance levels over time; therefore, the dose could be held constant indefinitely (e.g., over 20 years) (Dole 1980, 1988; Kreek 1973).
- Methadone was effective when administered orally, and because it has a half-life of 24–36 hours, it could be taken by patients once per day without the use of injection needles (Dole 1980, 1988; Dole et al. 1966; Kreek 1973).
- Most importantly, methadone relieved the narcotic craving or hunger described by addicts as a major factor in relapse and continued illegal heroin use (Dole 1980, 1988; Dole et al. 1966; Kreek 1973).
- Finally, the research indicated that methadone was medically safe and nontoxic (Kreek 1973, 1978). Methadone, like most opiate-class drugs, might cause minimal side effects. These effects would be experienced with greater frequency at the beginning of treatment and included constipation, excessive sweating, and decreased libido. Sweating appeared to be the most persistent effect. Constipation could be treated with diet or hydrophilic colloid and usually subsided. Libido usually returned to normal during the first months of treatment for the majority of patients; if not, an adjustment of the methadone dose could help to correct this particular complaint, although sexual problems, such as decrease in libido, were also associated with alcoholism, polysubstance abuse, or advancing age. While on methadone maintenance, female patients who may have had amenorrhea while addicted to heroin usually experienced normal menses.

The Expansion of Methadone Maintenance: From Research Project to Public Health Program

In 1965, under the guidance of Dr. Ray Trussell, Commissioner of the New York City Department of Hospitals, the initial research project on methadone safety and efficacy was expanded and transferred to the Manhattan General Hospital in New York City where a heroin detoxification program had previously been established. An impartial unit to evaluate the expansion and progress of methadone maintenance treatment was created at the Columbia University School of Public Health and Administrative Medicine, with Dr. Frances Rowe Gearing as the Chief of Evaluation. The Columbia University unit's work was reviewed by an independent committee composed of physicians and scientists chaired by Dr. Henry Brill. The committee recommended further evaluation, research, and expansion of the program (Joseph and Dole 1970).

In general, Gearing found that patients' social functioning improved with time in treatment as measured by decreases in and eventual elimination of heroin use and increased employment, school attendance, and homemaker status. Most patients were stabilized on 80–120 mg/day of methadone. Except for attempts by most new patients to "test the blockade," patients who remained in treatment curtailed and subsequently eliminated heroin use. However, about 20 percent or more of the patients entered treatment with serious alcohol and polysubstance abuse despite intake screening (Gearing and Schweitzer 1974). Treatment was continued for these patients when their conditions were discovered, and attempts were made to treat the alcoholism and polysubstance abuse.

The successful outcomes led to expansion of the program so that methadone maintenance became the major public health initiative for the treatment of heroin addiction. By 1992, approximately 115,000 patients were enrolled nationwide in methadone maintenance treatment programs.

Federal Leadership[2]

While Drs. Dole, Nyswander, Kreek, Lowinson, Gearing, Goldstein, Brill and others were continuing to understand the mechanisms of action and the therapeutic impact of methadone maintenance, events within the Federal government were occurring that would result in the rapid expansion of this treatment modality. In early 1970, the domestic advisors to President Nixon became concerned with the increasing evidence of heroin addiction's relationship to crime on the streets. The White House staff began to visit local treatment programs to examine the treatment programs that were available. Those they visited were all located within large metropolitan areas and had major components that were providing addiction treatment services using methadone maintenance. They were particularly impressed with the programs developed in the District of Columbia under the leadership of Dr. Robert DuPont.

The White House staff then commissioned two groups to provide policy and program recommendations for initiatives to respond to the increasing heroin addiction. One group was led by staff of the National Institute on Mental Health (NIMH) with collaboration from staff from the Office of Economic Opportunity (OEO), DEA, and the Department of Housing and Urban Development (HUD). The other was made up of professionals working in communities as program directors and researchers in drug addiction treatment. Both groups submitted lengthy papers containing their recommendations. The NIMH-led group recommended that methadone not be approved as a treatment, but that it should be subjected to further research. The nongovernmental advisory group espoused a strategy that would rapidly expand all forms of treatment and would extensively employ methadone maintenance.

This recommendation became Federal policy in June 1971 when the President named Dr. Jerome Jaffe as the Director of the Special Action Office for Drug Abuse Prevention (SAODAP). One of Dr. Jaffe's early goals was to promulgate FDA regulations that would govern the use of methadone to treat opioid addiction.

Prior to this policy decision, NIMH had been the locus of concern with researching and evaluating addiction treatment. During the late 1960s, NIMH provided support to the National Association for the Prevention of Addiction to Narcotics (NAPAN) as a cosponsor of the annual conferences concerning methadone maintenance. Additionally, Dr. Sidney Cohen, the Director of the Division of Narcotic Addiction and Drug Abuse at NIMH, obtained Investigational New Drug (IND) approval from FDA for methadone maintenance treatment. Under this IND, patient data were collected from all NIMH-funded treatment programs that chose to use methadone.

However, the use of a drug under an IND linked methadone treatment to a research status that could easily be revoked if policymakers so decided. Further,

while the IND permitted investigators to study agents that were not fully approved by FDA as safe and efficacious, there were no provisions for dealing with "investigators" who deviated from the proposed "protocols." During the late 1960s and early 1970s, there were a number of so-called investigators who chose to supply methadone to heroin addicts in large quantities with virtually no other services or monitoring. The behavior of the "investigators," motivated primarily by profits they made from charging addicts for treatment, led to considerable diversion of methadone. Two such investigators, one in Washington, D.C. and one in New York City, were particularly egregious, and their persistence demonstrated the inability of the IND model to limit the modality to legitimate practitioners.

At the same time, it became obvious that FDA was reluctant to grant approval to a treatment that had not followed the usual procedures of carrying out carefully structured double-blind studies on safety that met the requirements that FDA required of the pharmaceutical industry. Thus, on the one hand, it was obvious that the idea of methadone as "research" was no longer appropriate, because methadone benefited the patients and appeared to be safe; on the other hand, it would not be appropriate to approve methadone as an ordinary medication like a new antibiotic. Some new approach was needed that could make treatment available to heroin users who could benefit, but would allow government to prevent exploitation by unscrupulous practitioners.

Thus the first regulations were proposed in the early 1970s by FDA, with input from DEA, NIMH, and OEO, although they were never promulgated. These regulations were carefully crafted and were so restrictive that criticisms from within the Department of Health, Education and Welfare (DHEW), as well as from other levels of government, caused the regulations to be withdrawn. Later, with the advent of SAODAP, Dr. Jaffe, as the Director of that office, was able to insist that an acceptable set of regulations be published.

From that point on, even though the funding policies of the Federal government were modality neutral, many people accused the Federal government of being promethadone. However, analyses of the funding of drug programs by Federal agencies demonstrated that nonmethadone outpatient programs were more numerous than methadone maintenance programs and that Federal support for nonmethadone programs far exceeded that for methadone programs.

In the early 1970s, under the auspices of SAODAP, special monographs were published that set forth the recommended treatment regimen for methadone maintenance. These monographs attempted to place a greater emphasis on treatment and rehabilitation services than did the FDA regulations. The issues addressed included patient-counselor ratios, richness of service mix, urine screening, and dosage recommendations. Regrettably, these issues remain unresolved today despite 20 years of research and clinical experience to guide our patient care.

In 1974, Congress legislated a role for DEA in regulating methadone clinics. In 1980, NIDA and FDA formed an agreement to jointly develop and issue the methadone maintenance treatment regulations. Several modifications were made to the regulations during the 1980s as a result of information developed through extensive clinical care experience and research data uncovered by NIDA- funded investigators.

Also during recent years, reports by GAO, testimony by the Director of NIDA, and papers published by NIDA scientists and scientists working in other countries have all confirmed the safety, efficacy, and clinical benefit of methadone maintenance as an essential element in the spectrum of treatments for opioid addiction.

Today, with the concerns for the spread of the AIDS virus, treatment modalities that result in the reduction of high-risk behaviors, such as needle use, needle sharing, and the exchange of sex for drugs,are even more desirable. Methadone maintenance has established itself as an effective addiction treatment reducing risk factors related to HIV. This fact has given policy and program personnel additional reasons to consider expanding methadone maintenance treatment for the treatment of opioid dependence.

Criteria for Admission to Methadone Maintenance Treatment

Initially, criteria for admission to methadone maintenance treatment conformed to the requirements of a strict research protocol. Only addicts between the ages of 21 and 40 were admitted. The upper age limit was established on the basis of an unconfirmed theory that addicts "mature out" of addiction over age 40. Applicants had to be addicted to heroin for at least 4 years and had to have relapsed after previous attempts at treatment and detoxification. Addicts who were polysubstance abusers or alcoholics, and those with major psychiatric problems and medical problems such as TB, were not considered eligible. Initially, pregnant opioid-dependent patients were not admitted because

this was an investigation of a new medical procedure (Joseph and Appel 1985; Joseph and Dole 1970). The admission criteria were gradually modified to include previously excluded groups as methadone maintenance treatment proved successful and medically safe. Dr. Kreek's work was central to establishing the medical safety of methadone maintenance for all groups of patients.

Today, the FDA/NIDA regulations allow heroin addicts to be admitted with a 1-year addiction history including current physical dependence. The minimum age has been lowered to 18; however, applicants between 16 and 18 may be admitted if they have two prior attempts at detoxification or nonmethadone maintenance treatment and have parental consent or are declared emancipated before being admitted. The upper age limit has been removed since there are elderly addicts who have not "matured out" of addiction. Results of followup studies have shown that untreated addicts have high death rates, continue to use drugs after the age of 40, may be incarcerated, or may become seriously alcohol-dependent (Dole and Joseph 1978; Joseph and Appel 1985). Pregnant opioid-dependent women are now accepted and, with special medical justification, can be admitted under modified criteria (e.g., past history of addiction with current risk of readdiction, addicted to narcotics for less than 1 year but using at time of application). Applicants with major medical conditions and polysubstance abuse problems including alcoholism are also now eligible for treatment (Dole and Joseph 1978; FDA 1989; Joseph and Appel 1985; Gearing and Schweitzer 1974).

Treatment of Opiate Addiction as a Metabolic Disease

In the 1960s, researchers at The Rockefeller University began to question prevailing theories of addiction that were predicated on psychological attributes of addicted persons and conditioning theory. Dole and Nyswander (1967) indicated in an article addressing these ideas that heroin addiction may be a metabolic disease. Clinical and laboratory studies suggest that the relapse-provoking narcotic hunger is symptomatic of a metabolic dysfunction within the endogenous opiate receptor-ligand system that results from repeated use of opiates.

Although some patients function normally without medication after a period of treatment, the majority experience a return of drug hunger. If they do not reenter treatment, they are likely to relapse despite being motivated to remain abstinent and to attempt to function normally within the community. Therefore, methadone maintenance treatment is a corrective, not a curative, procedure of indefinite duration (Dole 1988; Kreek 1973, 1976).

Kreek studied subjects who detoxified from heroin or methadone and who succeeded in remaining abstinent from narcotics. She observed that during abstinence there are persistent abnormal neuroendocrine effects in both groups and has speculated that these abnormal responses in neuroendocrine functioning can contribute to relapse (Kreek 1986, 1988). With new analytic techniques available and the discovery of the specific ligands that bind to receptors, Dole supports the renewed interest in the study of the protracted abstinence syndrome (AS) (Kreek 1973, 1986).

Methadone Dose

As previously indicated, a blockade to the narcotic effects of all opiate-class drugs is achieved when methadone is prescribed within the range of 80–120 mg/day. This phenomenon was tested during the initial research by Dole, Nyswander, and Kreek at The Rockefeller University in a double-blind study. Patients were challenged for 4 weeks with heroin, morphine, Dilaudid, methadone, and a saline blank at different levels of stabilization and stages of narcotic tolerance. For patients maintained on 80–100 mg/day of methadone, the euphoric effects of all opiate-class drugs were abolished or inconsequential. The blockade was effective for the amount of heroin in several illegal bags that an addict would be able to purchase on the streets (Dole et al. 1966).

The public health implications of these findings were not apparent until large-scale studies were completed over long periods. These studies subsequently showed that patients maintained on doses of 70 mg/day or more made better adjustments than those maintained on lower doses. Hartel and coworkers (1988) analyzed about 190,000 urine toxicology reports for 2,400 methadone patients enrolled in an MMTP in the South Bronx over a 15-year period (1972–88). A trend line was discovered at the 70 mg/day level that held for the entire period: Those patients maintained on 70 mg/day or more stayed in treatment longer, used less heroin and other drugs, including cocaine, and had a lower incidence of AIDS and HIV infection. The effectiveness of methadone was more pronounced for patients maintained at 80 mg/day, especially for protection against HIV infection.

A series of research studies emerged that supported the

concept of a therapeutic effective dose range:

- A comprehensive study by Ball and Ross of six MMTPs in Baltimore, New York City, and Philadelphia showed that patients reduced their use of IV heroin by 71 percent compared with their preadmission level (Ball and Ross 1991). A study of IV heroin use of 407 patients over a period of 1 month showed that the higher the methadone dose, the lower the frequency of heroin use. About 27.9 percent of the 204 patients receiving 45 mg/day or less used heroin, while only 5.4 percent of the 203 patients maintained on doses greater than 45 mg/day did so. However, for those patients maintained on doses of 75 mg/day, no evidence of heroin use was found.
- In a review of 44 methadone maintenance programs, Watters and Price found that the level of dose was the single most important factor related to retention in treatment (the higher the dose, the longer patients stayed in treatment) (Appel unpublished).
- Caplehorn and Bell showed that retention in Australian programs increased by a factor of about two across each of three stratified levels of dose (<60 mg/day, 60–79 mg/day, and 80+ mg/day). Those patients stabilized at a blockade level of 80+ mg/day had longer periods of treatment than other patients. In this study, variables usually associated with good patient outcomes, such as employment status, educational level, and degree of criminality, appeared to have less of an impact than the patient's dose of methadone (Caplehorn and Bell 1991).
- In a review of the literature, Hargreaves indicated that patients appear to do better on higher doses in the range of 50 to 100 mg/day, especially at the beginning of treatment, and recommended that NIDA encourage State agencies to allow local programs to prescribe methadone up to a dose level of at least 100 mg/day (Hargreaves 1983).
- In a nationwide study of 172 randomly selected methadone maintenance treatment programs with a 72 percent response rate, D'Aunno and Vaughan found that about half of the programs encouraged patients to detoxify from methadone within 6 months after treatment admission. Sixty-eight percent of the programs set an upper limit for methadone doses at 50 mg/day, which is below the therapeutic effective dose recommended by GAO. As in other studies, the researchers found that patients maintained on higher doses of methadone remained in treatment longer. When patients participated in decisions related to dose and flexible take-home privileges, positive outcomes were more likely (longer duration of treatment and less illicit substance abuse). They recommended monitoring and, in certain cases, changing treatment practices of programs prescribing inadequate doses with minimal patient participation in decisionmaking. Programs treating high percentages of African-American patients, younger populations, and the unemployed appeared to have lower dose limits for patients, administered lower doses of methadone (on the average), may have encouraged patients to detoxify prematurely, and had less patient participation in decisions than other units (D'Aunno and Vaughan 1992).

Methadone Maintenance Treatment and the AIDS Epidemic

Injecting and noninjecting drug users, their sexual partners, and their offspring are at high risk for contracting HIV. The prevalence of HIV infection among patients entering methadone maintenance treatment varies depending on the program and its geographic location (Joseph and Springer 1990).

Several independent studies have shown that successful methadone maintenance treatment reduces risk behavior to contract and transmit HIV. Abdul-Quader and coworkers (1987) have reported that both the frequency of injection and the frequency of injection in shooting galleries were significantly reduced with time in methadone maintenance treatment. Studies from Uppsala, Sweden, and the South Bronx in New York City (Blix and Gröndbladh 1988; Hartel et al. 1988) showed that patients who entered methadone maintenance treatment before 1983 and continued in treatment had significantly lower rates of AIDS and HIV infection than patients who entered after 1983. Both studies suggested that methadone maintenance treatment may be associated with a reduced risk of contracting HIV and may offer protection to IDUs who are not yet infected.

Weber and coworkers (1990) conducted a 3-year prospective study in Switzerland that followed a group of HIV-infected methadone-maintained patients and a contrast group of HIV-infected heroin users who did not enter methadone maintenance treatment. The results showed that the progression of HIV to AIDS was slower among the methadone-maintained patients

than among the untreated heroin users. A significantly lower proportion of methadone-maintained patients progressed to AIDS compared with the untreated heroin users within the period of the study (24 percent versus 41 percent).

A study of 58 socially rehabilitated long-term methadone maintenance patients (employed, not using drugs, socially stable) showed that all were seronegative for antibody to HIV, but 91 percent had one or more markers of hepatitis B infection. These patients were enrolled in methadone maintenance treatment for approximately 16.9 years and were maintained on a median dose of 60 mg/day (range 5 to 100 mg/day). Prior to entering methadone maintenance treatment, individual patients had injected heroin for an average of 10.3 years and engaged in high-risk behaviors for contracting HIV (e.g., sharing needles, shooting drugs in shooting galleries, having sexual contacts with other substance abusers). Successful outcomes during methadone maintenance treatment in this group of patients were associated with an absence of HIV infection (Novick et al. 1990).

Medical Safety

Methadone Maintenance and the Immune System

Methadone doses administered for maintenance treatment or pain do not affect the functioning of the immune system. This fact is important to consider when treating HIV-infected patients. Untreated heroin addicts exhibit symptoms of compromised immune function similar to those observed in patients infected with HIV, such as reduced effectiveness of natural killer (NK) cells, enlargement of lymph nodes, and higher absolute numbers of CD cells. However, Kreek demonstrated in a study of 34 heroin addicts that the low levels of NK activity returned to normal in 53 percent of the subjects when placed on methadone (Kreek 1988).

In a study of parenteral heroin addicts, socially rehabilitated long-term methadone maintenance patients, and healthy nonaddicted controls, it was found that NK activity was significantly reduced among the heroin users. However, NK activity in the methadone-maintained patient and control groups did not differ. Also, the heroin users had absolute higher numbers of CD2, CD3, CD4, and CD8 positive cells than the patients and the controls (Novick et al. 1989). In an in vitro study of human peripheral mononuclear cells incubated with a wide concentration of methadone, it was found that NK activity was not affected by methadone concentrations in the plasma of maintained patients and patients under therapy for management of pain (Ochshorn et al. 1990). These studies appear to indicate that abnormalities of cellular immunity found among parenteral heroin users can be normalized when heroin users are placed on adequate doses of methadone, thereby strengthening the immune system response to infections such as HIV.

Methadone Maintenance and Pregnancy

It is important that pregnant heroin users be placed in treatment during the first trimester of pregnancy. Because heroin is a short-acting drug with a half-life of 4–6 hours, the fetus may be subjected to periodic daily episodes of withdrawal resulting in fetal stress and possible intrauterine death. Because of its long-acting duration, methadone, when prescribed in adequate doses, provides a relatively nonstressful environment in which the fetus can develop throughout pregnancy.

Entrance into methadone maintenance treatment during the first trimester of pregnancy is also associated with higher infant birth weights. There is evidence that methadone maintenance treatment, combined with prenatal services, may promote fetal growth, while continued use of heroin during pregnancy may result in infant morbidity (Kaltenbach and Finnegan 1992). However, the pregnant methadone-maintained patient may experience withdrawal symptoms and need an increase in the daily dose of the medication because of changes in metabolism and blood plasma levels of methadone, especially in the third trimester.

Kaltenbach and Finnegan have shown that there is no correlation between maternal dose of methadone, gestational age of neonate, weight in grams, and severity of the neonatal abstinence syndrome (AS). The neonatal syndrome may persist in phases of varying intensity during the first month after birth but can be successfully treated with paregoric. If the mother uses a variety of nonopiate drugs including alcohol, then phenobarbital, in addition to paregoric, may alleviate infant distress (Kaltenbach and Finnegan 1992).

Kaltenbach and Finnegan conclude that methadone does not impair the physical, emotional, or cognitive development of newborns when provided to pregnant substance abusers within an integrated program that addresses the mother's polysubstance abuse, medical, psychological, and social problems. Methadone maintenance treatment in pregnancy also contributes to the reduction of morbidity and mortality rates for both the mother

and child (Kaltenbach and Finnegan 1992).

Medical Complications and Medical Safety

Kreek has demonstrated that methadone prescribed in high doses has no toxic effects and minimal side effects. Medical complications identified among methadone-maintained patients include chronic illness that existed prior to treatment or coexisting medical problems and conditions, such as chronic alcoholism, polysubstance abuse (cocaine and other drugs), HIV infection, and AIDS. Other conditions prevalent at time of admission to treatment include chronic liver disease, TB, and syphilis. Patients may also suffer from various forms of trauma and malnutrition. The effects of chronic alcoholism (e.g., cirrhosis and other liver disease) are a major medical problem among patients.

The patient's health may be poor at the time of admission to methadone maintenance treatment. However, for those who remain in treatment, health status generally improves unless the patients have AIDS, cancer, and other illnesses with high mortality rates. There are few contraindications for treating methadone maintenance patients with serious conditions. However, methadone maintenance patients treated with rifampin for TB may experience withdrawal symptoms and need to be maintained on higher doses of methadone or prescribed an alternate medication for the treatment of TB. Also, patients cannot be treated with drugs classified as antagonists (such as naloxone) or analgesics that combine agonist/antagonist properties (such as Talwin). Using these drugs will precipitate withdrawal symptoms.

Since 1986, the number of cases of multidrug-resistant TB associated with homelessness and HIV infection has increased. Subsequently, TB has emerged as a major public health problem within methadone maintenance programs. Many clinics now dispense medications for the treatment of AIDS (e.g., AZT) and TB and provide treatment for alcoholism and cocaine addiction in addition to dispensing methadone. Admissions of women, many of whom are pregnant and in ill health, have also increased. Many programs are now developing special initiatives for pregnant women to ensure they are enrolled in prenatal care.

Other Concerns

Employment

In the 1960s and early 1970s, many of the patients were still able to obtain well-paying blue collar jobs. The Federal Rehabilitation Act of 1973 and parallel State human rights laws protected individuals in methadone maintenance treatment from employment discrimination solely on the basis of their past drug record and participation in treatment. The right of individuals in MMTPs to hold jobs, even safety-sensitive jobs, has been upheld in several cases under the Rehabilitation Act (*Davis v. Bucher* 1978; *Doe v. New York City Transit Authority* 1987).

Protection against discrimination under the Rehabilitation Act and the more recent Americans with Disabilities Act is very important because the Supreme Court had held in *Beazer v. New York City Transit Authority* (1978) that excluding methadone-maintained individuals from all jobs within the Transit Authority did not violate equal protection under the constitution. In this ruling, the Supreme Court overturned two lower court decisions that had found that individuals maintained on methadone should not be excluded from all jobs. Unfortunately, scientific research documenting that methadone-maintained patients can function without impairment was either ignored or not fully understood. However, the statutory protections of the Rehabilitation Act and the Americans with Disabilities Act make the Beazer decision virtually irrelevant.

Nevertheless, with the change to service-sector employment during the past decade, it has become increasingly difficult to place patients without the required education and skills in jobs that pay well. Furthermore, employment opportunities for many patients have been reduced by the economic recessions of the past decade, and the employment rate for methadone maintenance patients has declined in inner cities. To help patients obtain employment in a changing job market, vocational assessment and counseling have become important social components of treatment.

Homelessness has also affected a number of patients, especially those living in inner-city ghettos. Patients who have refused to go to shelters have been found sleeping in subways and other public places. Counselors have, therefore, assumed responsibility for helping homeless patients to obtain living quarters through referrals to community agencies.

Social Stigma

Unfortunately, the general public and some professionals have disparaged and trivialized methadone maintenance treatment as "just substituting one drug for another." These attitudes negatively affect programs in many ways, but it is the methadone maintenance patients themselves who are most stigmatized and harmed, irrespective of what they have accomplished. Therefore, they remain hidden, ashamed of being enrolled in a program that has helped them, and fearful of social ostracism and loss of employment. According to Cooper (1992), misunderstandings about the

disease of addiction, the role of methadone maintenance treatment, and the stigma associated with the program may underlie counterproductive practices within the program, such as prescribing lower than effective doses of methadone. To dispel myths and misunderstandings about the use of methadone in the treatment of heroin addiction, it is important that the public, professionals, and the patients themselves be educated, and that outreach programs be developed for untreated addicts.

Summary

Heroin injection and its sequelae, both personal and social, generate many of the major public health and social problems facing the United States today. As in past epidemics, effectively treating the infected individual and the individual at risk are prime concerns of public health policy. Methadone maintenance treatment has the potential to achieve both goals by treating narcotics addicts who compulsively use drugs, perpetuate illicit drug use, and act as vectors for the transmission of HIV, STDs, TB, hepatitis, and other infectious diseases.

Effective methadone maintenance treatment has the potential to remove individuals from trajectories that support destructive behavior. This modality also has the potential to provide the necessary pharmacological, psychological, and social supports to help individuals improve their lives. If methadone maintenance treatment is to reach its potential, outreach and educational programs, the development of need-related services, and evaluation are necessary.

The major public health strategy for methadone maintenance programs is to develop flexible intake procedures to admit without delay the large number of untreated addicts who need and apply for treatment and to ensure that relevant services are available to meet their needs. These goals challenge policymakers as well as health and social service workers. Neglecting problems that face many untreated heroin addicts and methadone maintenance patients affects, and will continue to affect, the quality of life in the United States.

References

Abdul-Quader, A.S.; Friedman, S.R.; Des Jarlais, D.C.; Marmor, M.M.; Maslansky, R.; and Bartelme, S. Methadone maintenance and behavior by intravenous drug users that can transmit HIV. *Contemporary Drug Problems* (Fall 1987):425–433, 1987.

Appel, P. Treatment issue report #56: Review of a NIDA grant. The relationship of treatment policy to client retention, by Watters, J.A., and Price, R.H. Bureau of Research and Evaluation, University of Michigan. Unpublished internal report of the New York State Division of Substance Abuse Services.

Ball, J.C., and Ross, A. The Effectiveness of Methadone Maintenance Treatment. New York: Springer-Verlag, 1991.

Beazer v. *New York City Transit Authority*, 440 U.S. 568 (1978).

Blix, O., and Gröndbladh, L. AIDS and IV heroin addicts: The preventive effect of methadone maintenance in Sweden. Abstract 8548. Fourth International Conference on AIDS, Stockholm, Sweden, 1988.

Brecher, E.M. Licit and illicit drugs. In: *Consumers Union Report on Narcotics, Stimulants, Depressants, Inhalants, Hallucinogens, and Marijuana*. Boston, MA: Little, Brown and Company, 1972.

Caplehorn, J.R.M., and Bell, J. Methadone dosage and retention of patients in maintenance treatment. *Medical Journal of Australia* 154(February 4):195–199, 1991.

Cooper, J.R. Methadone treatment in the United States. In: Awni, A., and Westmermeyer, J., eds. *Methadone in the Management of Opioid Dependence: Programs and Policies Around the World*. Geneva, Switzerland: World Health Organization, 1988.

Cooper, J.R. Ineffective use of psychoactive drugs: Methadone treatment is no exception. *Journal of the American Medical Association* 267(2):281–282, 1992.

Courtwright, D.T. *Dark Paradise: Opiate Addiction in America Before 1940*. Cambridge, MA: Harvard University Press, 1982.

Courtwright, D.T.; Joseph, H.; and Des Jarlais, D. *Addicts Who Survived: An Oral History of Narcotic Use in America, 1923–1965*. Knoxville, TN: University of Tennessee Press, 1989.

D'Aunno, T., and Vaughn, T.E. Variations in methadone treatment practices. *Journal of the American Medical Association* 267(2):253–258, 1992.

Davis v. *Bucher*, 451 F., supp. 791 (E.D.Pa. 1978).

Doe v. *New York City Transit Authority*, 85 Civ. 4521 (S.D.N.Y. 1987) (Consent Degree).

Dole, V.P. Addictive behavior. *Scientific American* 243(6)(December):138–154, 1980.

Dole, V.P. Implications of methadone maintenance for theories of narcotic addiction. *Journal of the American Medical Association* 260(20) (November 25):3025–3029, 1988.

Dole, V.P., and Joseph, H. Long-term outcome of patients treated with methadone maintenance. *Annals of the New*

York Academy of Sciences 311:181–189, 1978.

Dole, V.P., and Nyswander, M.E. Heroin addiction: Metabolic disease. *Archives of Internal Medicine* 120:19–24, 1967.

Dole, V.P.; Nyswander, M.E.; and Kreek, M.J. Narcotic blockade. *Archives of Internal Medicine* 118(October):304–309, 1966.

Food and Drug Administration. FDA Regulations in the Federal Register. 21 CFR Part 21. Washington, DC: Food and Drug Administration, March 2, 1989.

Gearing, F.R., and Schweitzer, M.D. An epidemiologic evaluation of long-term methadone maintenance treatment for heroin addiction. *American Journal of Epidemiology* 100:101–112, 1974.

Gewirtz, P.D. Notes and comments: Methadone maintenance for heroin addicts. *The Yale Law Journal* 78:1175–1211, 1969.

Hargreaves, W.A. Methadone dose and duration for maintenance treatment. In: *Research on the Treatment of Narcotic Addiction: State of the Art*. National Institute on Drug Abuse Research Monograph. DHHS Pub. No. (ADM)97-1281. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1983. pp. 19–92.

Hartel, D.; Selwyn, P.A.; and Schoenbaum, E.E. et al. Methadone maintenance treatment and reduced risk of AIDS and AIDS-specific mortality in intravenous drug users. Abstract No. 8546. Fourth International Conference on AIDS, Stockholm, Sweden, June 1988.

Inciardi, J.A. Some considerations in the clinical efficacy of compulsory treatment: Reviewing the New York experience. In: *Compulsory Treatment of Drug Abuse: Research and Clinical Practice*. National Institute on Drug Abuse Research Monograph 86. 1988. pp. 126–138.

Joseph, H. The criminal justice system and opiate addiction: A historical perspective. In: *Compulsory Treatment of Drug Abuse: Research and Clinical Practice*. National Institute on Drug Abuse Research Monograph 86. 1988. pp. 106–125.

Joseph, H., and Appel, P. Alcoholism and methadone treatment: Consequences for the patient and the program. *American Journal of Drug and Alcohol Issues* II(1,2):37–53, 1985.

Joseph, H., and Dole, V.P. Methadone patients on probation and parole. In: *Federal Probation* June 1970. pp. 42–48.

Joseph, H., and Springer, E. Methadone maintenance treatment and the AIDS epidemic. In: *The Effectiveness of Drug Abuse Treatment: Dutch and American Perspectives*. Malabar, FL: Robert E. Krueger, 1990. pp. 261–274.

Kaltenbach, K., and Finnegan, L.P. Methadone maintenance during pregnancy: Implication for perinatal and developmental outcome. In: T. Sonderegger, ed. *Perinatal Substance Abuse: Research Findings and Clinical Implications*. Baltimore: Johns Hopkins University Press, 1992.

Kreek, M.J. Medical safety and side effects of methadone in tolerant individuals. *Journal of the American Medical Association* 223(6):665–668, 1973.

Kreek, M.J. Medical complications in methadone patients. *Annals of the New York Academy of Sciences* 311(Dept. 29):110–134, 1978.

Kreek, M.J. Tolerance and dependence: Implications for the pharmacological treatment of addiction. In: Harris, L.S., ed. *Problems of Drug Dependence* (Proceedings of the 48th Annual Scientific Meeting, of the Committee on Problems of Drug Dependence). DHHS Pub. No. (ADM)87-1508. Rockville, MD: National Institute on Drug Abuse, U.S. Department of Health and Human Services, 1986. pp. 53–62.

Kreek, M.J. Summary of presentation at 1988 meeting of the Committee for Problems of Drug Dependence. *NIDA Notes* Fall: 12, 25, 1988.

Kreek, M.J. Multiple drug abuse patterns and medical consequences. In: Meltzer, H.Y., ed. *Psychopharmacology: Third Generation of Progress*. New York: Raven Press. pp. 1597–1904.

Maddux, J.F. Clinical experience with civil commitment. In: *Compulsory Treatment of Drug Abuse: Research and Clinical Practice*. National Institute on Drug Abuse Research Monograph 86. 1988. pp. 35–56.

Novick, D.M.; Joseph, H.; and Croxson, T.S. et al. Absence of antibody to human immunodeficiency virus in long-term, socially rehabilitated methadone maintenance patients. *Archives of Internal Medicine* 150(January):97–99, 1990.

Novick, D.M.; Ochshorn, M.; and Ghali, V. et al. Natural killer activity and lymphocyte subsets in parental heroin abusers and long-term methadone maintenance patients. *Journal of Pharmacology and Experimental Therapeutics* 250:606–610, 1989.

Ochshorn, M.; Novick, D.M., and Kreek, M.J. In vitro studies of the effect of methadone on natural killer cell activity. *Israel Journal of Medical Sciences* 26(8):421–425, August 1990.

Weber, R.; Ledergerber, B.; Opravil, M.; and Luthy, R. Cessation of intravenous drug use reduces progression of HIV infection in HIV+ drug users. Abstract of the Sixth International Conference

on AIDS, San Francisco, June 1990.

For Further Reading

Ball, J.C., and Ross, A. *The Effectiveness of Methadone Maintenance Treatment.* New York: Springer-Verlag, 1991.

Brecher, E.M. *Licit and Illicit Drugs.* Boston: Little Brown and Company, 1972.

Committee for the Substance Abuse Coverage Study, Division of Health Care Services, Institute of Medicine. *Treating Drug Problems.* Vol. 1. Gerstein, D.R., and Harwood, H.J., eds. Washington, DC: National Academy Press, 1990.

Courtwright, D.T.; Joseph, H.; and Des Jarlais, D. *Addicts Who Survived: An Oral History of Narcotic Use in America, 1923–1965.* Knoxville, TN: University of Tennessee Press, 1989.

Dole, V.P. Addictive behavior. *Scientific American* 243(6):138–154, 1980.

Dole, V.P. Methadone maintenance from a public health perspective. April 30, 1989. Report available from Dr. Dole, The Rockefeller University, New York City.

General Accounting Office Report. *Methadone Maintenance.* GAO/HRD-90-104, 1990.

Hartel, D. Cocaine use, inadequate methadone dose increase risk of AIDS for IV drug users in treatment. *NIDA Notes* 5(1)(Winter), 1989/1990.

Hartel, D.; Schoenbaum, E.E.; and Selwyn, P.A. et al. Temporal patterns of cocaine use and AIDS in intravenous drug users in methadone maintenance. Paper presented at the 5th International Conference on AIDS, Montreal, Canada, June 1989.

Musto, D.F. *The American Disease: Origins of Narcotic Control.* New York: Oxford University Press, 1987.

National Institute on Drug Abuse. *Extent and Adequacy of Insurance Coverage for Substance Abuse Services (Institute of Medicine Report: Treating Drug Problems).* Vol. II. Drug Abuse Services Research Series, No. 3. DHHS Pub. No. (ADM)92-1989. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1992.

The Office of Substance Abuse Services. Methadone Position Paper. Lansing, MI, 1990.

Rosenblum, A.; Magura, S.; and Joseph, H. Ambivalence towards methadone treatment among intravenous drug users. *Journal of Psychoactive Drugs* 23(1):21–27, 1991.

Endnotes

1. The Treasury Department's antimaintenance position was upheld in two cases before the Supreme Court in 1919; *Webb et al. v. United States* and *United States v. Doremus.* Two subsequent cases repudiated the Webb decision (*Lindner v. United States* (1925) and *Boyd v. United States* (1926); however, the Narcotics Division of the Prohibition Unit of the Treasury Department chose to adopt the antimaintenance position as set forth in the Doremus and Webb decisions.

2. This section on Federal leadership was prepared by Karst J. Besteman, Director and Principal Investigator, Institutes for Behavioral Resources, Inc., Substance Abuse Center, Washington, D.C.

Chapter 3—Review of Clinical Issues

Joan Ellen Zweben, Ph.D.

The task of improving methadone maintenance treatment will require a long-term effort with careful planning to coordinate development along a range of dimensions. While goals such as improving the climate surrounding methadone maintenance treatment, disseminating information about sound treatment practices, upgrading staff skills, and implementing appropriate evaluation methods cannot be achieved by short bursts of effort, they are quite feasible given our current level of knowledge. Methadone maintenance treatment is more thoroughly researched than any other drug treatment modality, yet the fruits of this effort are slow to be used and accepted in decisionmaking. Treatment efforts have been steadily undermined by reduced funding and then further penalized for being ineffective. Resources should be augmented and selectively applied to upgrade the quality of care.

Improving the Climate

There is no question that a major barrier to effective methadone maintenance treatment has been the attitudes surrounding heroin addicts and the providers who work with them. Heroin addiction remains both feared and scorned, although alcohol and tobacco, two legal drugs, are associated with far greater societal cost. Both methadone-maintained patients and methadone maintenance treatment providers continue to feel their endeavor is stigmatized, and this attitude influences how staff and patients view their own possibilities and progress. It also affects the level of talent attracted to the effort, the length of time staff remain committed to working in methadone maintenance treatment, and the amount of resources brought into the field. This situation has been improved by documentation of the many ways in which methadone maintenance treatment provides valuable leverage in the AIDS epidemic, but there is still a long way to go.

The Interface Between Regulations and Clinical Care

Creating an accountability system that does not defeat its intended purpose is a complex problem requiring regulatory bodies and care providers to collaborate. Some regulations, although intended to foster quality care, are based on the premise that a patient's behavior can be adequately controlled through rules.

This idea often conflicts with the clinician's need to establish a therapeutic alliance and conflicts with most addiction treatment professionals' understanding that one person is fundamentally powerless to control the drug use of another. It is essential for programs to be able to set firm limits without being punitive. However, good treatment ultimately rests on collaboration between the patient and provider and reflects an appreciation of the need to promote autonomy and responsible decisionmaking on the part of the patient.

Many of the constraints evolved in an effort to bring some accountability into programs and ensure quality care. Efforts to reduce subjective interpretation of program practices often have led to emphasis on technical compliance with regulations that could be monitored objectively. In contrast, a regulatory strategy could be developed that rewards rather than penalizes programs willing to tackle difficult clinical problems.

NIDA is currently conducting a feasibility study—MTQAS—to explore a system that would focus on measuring program performance rather than process as a means of determining effectiveness of MMTPs. The proposed methodology attempts to account for variables that affect outcome, such as the program's case-mix and patient demographics, employment opportunities, and cocaine use in the community and avoids simply comparing results at one clinic with those of another. If this effort succeeds, it may provide a way to

judge MMTPs by the results of their efforts. In any case, it may be time to review existing State regulations to determine if they produce their intended effect.

Developing an Effective Counseling Component

A growing body of evidence indicates that intensifying treatment produces better outcomes, both in reducing illicit drug use and facilitating lifestyle changes. Historically, drug counseling available in the clinics has had an external focus—managing the patient's life problems. The counselor's task has been to identify and address specific problems in the areas of drug use, physical health, interpersonal relationships, family interactions, and vocational or educational goals; perform the role of case manager and be a liaison between physicians and medical institutions, courts, and social services; perform more typical counseling functions, such as providing initial screening for medication and other program services and helping the patient to develop coping strategies for current problems; and attend to issues concerning program rules, privileges, and policies.

The treatment plan can provide structure to counseling sessions and be a tool to monitor progress. It should specify the level, duration, and frequency of counseling, and events (like case conferences and emerging patient crises) that produce changes in those arrangements. Treatment plans should be individualized and should contain short- and long-term goals as well as a documented statement of the specific issues or obstacles. Documentation should reflect the uniqueness of the patient's struggle as well as compliance with uniform requirements. When possible, computerized recordkeeping systems should be used to simplify recordkeeping and track data useful for clinical and administrative management.

Counseling frequency has often been specified by regulation in the absence of data about whether it is necessary or effective with all patients. Frequently, counselors expend so much effort pursuing resistant patients in order to comply with the mandatory number of patient counseling contacts often required by State regulations that they do not have enough time to address the needs of those who want and/or need more help. MMTPs should develop protocols to monitor the patient's continued drug-free status and involvement in constructive activities. The protocols should also incorporate behaviors that signal possible relapse. Patients who remain free of illicit drug use and constructively involved could be seen in a medical maintenance model, leaving more counseling time for patients in the beginning stages of treatment or those who demonstrate a need for more intensified effort.

Drug counseling efforts appear to yield benefits as long as the patient does not also have a significant coexisting psychiatric disorder, in which case other resources need to be added. Recent large-scale epidemiological studies indicate that over 50 percent of drug users who present themselves for treatment have a coexisting psychiatric disorder (Regier et al. 1990). Smaller studies confirm the prevalence of these disorders in the methadone maintenance population. Other empirical studies indicate that when global psychiatric status ratings of the patient indicate severe impairment, supplemental professional psychotherapy can significantly improve the treatment outcome (Woody et al. 1983).

The boundary between counseling and psychotherapy is often ambiguous; however, in general, psychotherapy focuses on intrapsychic processes that impair effective coping and damage relationships. The supportive-expressive therapeutic approach emphasizes identifying and resolving problematic relationship themes. Cognitive-behavioral therapy focuses on uncovering and understanding the relationship between automatic thoughts and underlying assumptions on problematic feelings and behaviors. Both approaches have benefits. A positive relationship with the therapist consistently emerges as an important variable but must be combined with special knowledge and skills. In most States, psychotherapists are credentialed and licensed. Psychotherapists supplement but do not replace the drug counselor and should be fully integrated into the overall program. This means they need to be familiar with methadone maintenance and be able to work well with other staff members. It should never be assumed that credentials or licenses qualify a psychotherapist to work within addiction treatment, much less methadone maintenance, as graduate training has been slow to incorporate addictive disorders as an integral part of professional training.

Programs need access to clinicians with sophisticated diagnostic skills to identify patients with coexisting psychiatric disorders. Programs should develop mechanisms to coordinate drug counseling with professional psychotherapy if these services are provided by different individuals, and, because medication can be a useful tool, should have access to physicians with knowledge of appropriate prescribing practices for an addicted population. It is

essential that these physicians and the day-to-day treatment providers communicate well.

Because there appears to be a relatively high incidence of depression in the opioid-dependent population, it is particularly important for programs to address this issue more systematically. The effectiveness of antidepressant medication and its safe interaction with methadone is known, but this information needs to be disseminated to programs more rapidly than at present. Although psychotic conditions occur relatively less frequently, it is common for clinics to have some highly disturbed patients among their populations; thus, it is important for staff to be able to recognize and manage these patients appropriately.

Patients should also have ready access to vocational evaluation, referral, and training programs. Research into the efficacy of vocational programs indicates that successful interventions should be integral to the treatment program's collective mission.

Patients with children need to be exposed to intense parenting training workshops because so many patients in MMTPs grew up in abusive families. A well-designed parenting class sequence includes information, skill training, and the opportunity to explore issues. These workshops are often well received by parents who feel the absence of role models and skills and are important to reduce the cross-generational transfer of alcohol and substance abuse. Coordinated aftercare programs in conjunction with self-help models can better ensure sustained recovery from long-term narcotic addiction.

Continued Heroin, Alcohol, and Other Drug Use

It is relatively common for patients to continue their heroin use after they are admitted to treatment and to reduce it slowly over time. It is important to remember that methadone maintenance patients frequently have a long history of opioid addiction—addressing the physiological component is only the beginning. Participation in a social network revolving around drugs, suppressing traumatic memories of physical or sexual abuse, and coping with painful feelings in the same way as did several generations of family members are only a few of the reasons why patients do not immediately discontinue heroin use once on methadone. Most of the important issues require long-term work, and clinicians need to be clear and firm about what they expect.

It is particularly important that regulatory constraints setting arbitrary guidelines and timetables do not impair the clinician from dealing effectively with the patient. Specific timetables (e.g., patient must be discharged if cocaine use does not cease within 3 months) are usually inappropriate to the clinical realities. Instead, such limits should be formulated on a case-by-case basis, with an appreciation of the need to foster retention to improve outcome. In any case, the discharge option should be exercised only when staff have exhausted all alternatives and when it is clear that discharge constitutes the lesser harm (see ch. 8).

A common problem in methadone maintenance treatment settings is that staff and patients alike assume that discontinuation of injecting drug use is the sole focus of the treatment effort. While cocaine use evokes alarm because it clearly undermines patient stability, other illicit drug use, such as marijuana, may be overtly or covertly viewed as a lesser evil unless there is clear evidence of impaired functioning. Alcohol use is regarded by most entering patients as entirely acceptable because it is legal. Changing these attitudes and the norms that grow up around them requires patience and sustained effort.

Programs can begin to change these attitudes in a variety of ways through activities that repeatedly emphasize that heroin use is only the most obvious part of the problem and that the real issue is the role of intoxicants (legal and illegal) in the patient's life. Patients need to get the message on admission and throughout treatment that if they want methadone maintenance treatment to work well for them, they must recognize that alcohol and other drug use will undermine their progress. Both staff and patients need to be educated on ways in which this occurs and supported in envisioning an intoxicant-free lifestyle. Because many patients grew up in families in which alcohol and other drugs were used for one or more generations, it can be expected that they will embrace with difficulty the notion of a lifestyle free of these drugs. It is often forgotten that many AA members contemplated attending a meeting for years before they actually did it and attended meetings for long periods before participating wholeheartedly. There is no reason to expect that methadone maintenance patients will progress more rapidly. The concept of enabling has often been inappropriately applied to discourage staff from setting realistic goals and being willing to address complex clinical problems in a problem-solving manner. Given our understanding of the importance of improving retention in order to promote a positive outcome, a policy of discharge for

other drug use is usually not clinically appropriate (see ch. 8 for further discussion).

Issues for Women Patients

The AIDS and cocaine epidemics have brought renewed focus to issues that impact women and have increased somewhat the resources brought to bear on women's problems. Many women enter treatment with a long history of childhood physical and sexual abuse and describe current manifestations of victimization and brutalization in their lives. Once the patient is stabilized and her practical needs more or less taken care of, counseling frequently centers on a patient's intimate relationships, which are often conflictual and constitute primary relapse hazards. Because addicted women rarely have highly paid roles in the drug-dealing network, prostitution is common and also negatively influences intimate relationships.

Within sexual relationships, safety from the AIDS virus may be difficult to secure. Addicted women's sexual partners are often other IDUs who may be infected or who engage in behavior that may lead to infection. Many women are uninformed or unwilling to raise the issues of safer sex or safer needle use, often fearing everything from rejection to physical violence if they press their partners to use condoms or other barrier methods or clean their needles. Hence, among women we are seeing an accelerating rate of HIV and other STDs, which in turn increase the risk of infection in newborns.

Child care responsibilities form a major obstacle to consistent participation in treatment. Economic and regulatory obstacles need to be surmounted to make child care more readily accessible to parents in treatment.

Methadone maintenance treatment has the capacity to provide optimal, comprehensive, and intensive services for the opioid-dependent pregnant woman. Methadone maintenance treatment removes the addicted woman from the drug-seeking environment and eliminates the need for illegal behavior. In addition, methadone maintenance treatment can provide access to prenatal care, maternal nutrition, and psychosocial rehabilitation. When appropriate care can be provided, the outcome for the child is markedly improved. These issues are addressed extensively in a separate chapter in this volume.

Family planning practices also need to be addressed, as many women confuse infertility with the amenorrhea, which often results from the addict's lifestyle. Methadone normalizes endocrine function, and it is not unusual for women in early stages of treatment to become pregnant, although they had been sexually active without contraceptives for years with no such result. Surprise and unplanned pregnancies can be reduced by educating the patient early in treatment, with the counselor following up to enhance implementation of effective practices.

Methadone Maintenance Treatment and HIV-Spectrum Disease

It is now generally agreed that methadone maintenance treatment can play a key role in decreasing HIV infection. Attracting people to treatment provides a means to reduce needle use. Patients who come for methadone withdrawal can be offered HIV screening, education, and limited counseling. Those who participate also have a continuing forum to discuss their concerns and resistances to practicing safer sex and sound needle-cleaning procedures if they are still using drugs. The treatment effort has a cumulative positive benefit over time, as the abstinent addict can better exercise good judgment than the intoxicated one.

Research reports indicate that the longer patients have been in methadone maintenance treatment, the lower the rate of seropositivity for HIV. These patients show better immune system functioning and reduced injecting drug use and needle-sharing practices. Rigorous studies on methadone indicate it is a safe pharmaceutical product that produces no organic dysfunction and normalizes functions (such as the endocrine function in the menstrual cycle) impaired by street drug use. More specific studies suggest that methadone has no adverse immunosuppressant effects on patients in treatment.

Several model programs that fully integrate AIDS-related activities into methadone maintenance treatment exist. This knowledge should be made readily available to other programs through technical assistance. Certainly counselors need specialized training to address the dilemmas patients with HIV-spectrum disease face (see ch. 10). The counselor should first handle the initial denial, shock, and/or anger a patient experiences on receiving a positive test result; the counselor should then encourage the patient to mobilize in a healthy direction instead of into self-destructive behavior. As the disease progresses, the counselor should address the practical problems created by dementia and physical symptoms and help the patient develop compensatory strategies. Staff should be supported in their distress concerning patients they may care a great deal about who gradually sicken and die in the course of their

work together. Specialized recovery groups and self-help meetings can be developed on-site and in the community. These groups should preserve the view that methadone maintenance treatment is compatible with self-help programs of recovery.

Methadone Maintenance Patients in Self-Help Programs

Participation of methadone maintenance treatment patients in 12-step and other self-help programs is a complex issue that needs to be carefully considered. Historically, many methadone maintenance treatment patients attended AA meetings as a way of addressing their alcoholism, found them helpful, and encouraged others to attend. Increasing recognition of the benefits of such participation has led to a variety of ways to bring methadone maintenance treatment and self-help programs closer together. To understand some of the inherent difficulties, it is important to keep in mind that these are self-help groups with a long tradition of seeking to minimize hierarchy, authority, and organization. For example, although the General Service Office of AA may issue and distribute literature, such as the pamphlet *The A.A. Member—Medications and Other Drugs* (1984), local groups retain their grassroots character and members may vigorously espouse views that are inconsistent with AA literature. This situation can produce difficult experiences for patients seeking this form of support.

Methadone maintained patients have frequently been made to feel unwelcome and ostracized from the mainstream of 12-step programs. Many, unable to handle such rejection, have chosen not to return; some angrily dismiss the program as a whole. These difficulties often present a justification for self-medication, so the clinician's decision to press the patient's participation entails some risk. In some communities, problems are more likely to occur in NA than AA. In any case, staff can direct the patient to meetings that are more hospitable through clinic newsletters, bulletins, and staff communications. However, it is probably undesirable to require the patient to participate in 12-step or other self-help programs, as the issues encountered can be very complex and clinicians need a relatively free hand to work them out.

The charged reaction of many 12-step program members to methadone has encouraged the formation of specialized meetings for methadone maintenance patients, most often at the treatment site. There is little question that the self-help process can help generate a support system of nonusers and provide tools for fostering personal development. However, some cautions are in order.

Many years of research suggest there is a sizeable subgroup of methadone maintenance patients who need to remain on drug replacement therapy in order to maintain their gains; thus, it is important that the meeting emphasize progress in recovery, whether the patient is eventually able to taper off methadone or not. It has been proposed that methadone be viewed as simply another medication and that a patient be considered abstinent if he or she does not use illicit psychoactive drugs, inappropriately use licit psychoactive drugs, or continue to use any substance despite known adverse consequences. Thus, the patient who is not using illicit drugs, but is taking other drugs as prescribed, is in recovery, particularly if his or her functioning is improved rather than impaired. This view emphasizes lifestyle changes and responsible functioning and is consistent with the AA position in its publication, *The A.A. Member—Medications and Other Drugs*. Thus, participating in a self-help program can be considered appropriate whether the patient is planning to taper off methadone or not.

Vigorous efforts to educate the patient population, treatment providers, and the public will be required to elucidate this position. Perhaps such efforts could be synchronized with those aimed at influencing attitudes about psychotropic medication prescribed for patients with coexisting ADM disorders. Although initially arduous, the long-term benefit of increasing access to these self-help groups is enormously important.

A number of creative strategies have evolved to promote use of self-help meetings. One is to provide a simulated meeting on-site to introduce patients to the language, customs, and rules of the group and to generate enthusiasm about possible benefits of participating. Teaching patients what to expect and explaining the history and rationale of common practices increases their comfort level and understanding and diminishes resistance. A second approach is to encourage the development of self-help models more specifically geared to methadone maintenance patients. In these models, existing materials can be modified and others introduced. This approach should not be considered a replacement for fostering participation in traditional self-help programs. Although the approach permits tailoring to some of the unique needs and concerns of methadone maintenance patients and reduces their sense of being "second best" because they are on methadone, its drawback is that it

will not provide the range of resources available through traditional self-help programs in most communities. The sheer number and frequency of traditional meetings and related activities provide a potentially more comprehensive support structure for the patient who is able to make use of them.

It is hoped that in time both methadone and psychotropic medications (as well as other appropriate medications, such as disulfiram (Antabuse) and naltrexone (Trexan)) will be accepted in self-help programs as being fully compatible with recovery. This acceptance will permit an extremely important element in the recovery process to emerge: the methadone maintenance patient who is a highly visible role model and who can be an example to others striving for recovery. Currently, patients who are doing well are extremely reluctant to make themselves visible in any public forum because of the stigma and negative attitudes surrounding methadone maintenance.

In summary, the integration of self-help programs into methadone maintenance treatment is one of the most exciting recent developments. However, it is important that patients be encouraged rather than required to participate because the programs are akin to those of two disparate cultures beginning to come to terms with each other, and this accommodation process cannot thrive under mandates and constraints.

Discontinuation of Methadone

It is unfortunate that the success of methadone maintenance treatment continues to be judged by what happens once it is discontinued, and it is increasingly clear that this criterion rests on questionable assumptions. Initially, many hoped that methadone maintenance could provide a moratorium during which lifestyle changes could be effected and after which methadone could be discontinued; however, an abundance of empirical evidence suggests otherwise. Although short-term abstinence is common, it appears that only 10–20 percent of patients are able to achieve long-term abstinence once methadone maintenance treatment is discontinued. It increasingly appears that the characteristics of this particular addictive disorder may indicate long-term drug replacement, at least until alternative biochemical interventions can be identified.

The psychosocial characteristics of those who are able to successfully discontinue methadone maintenance treatment have been studied, with the aim of assisting others to get off methadone. Remaining opioid-free requires addressing personality patterns, family issues, job skills, friendship patterns, health practices, and recreational activities, among other issues. In this author's experience, patients express intense fear of even attempting to taper off, a fear that appears justified given low long-term success rates. It also seems likely that physiological differences are a crucial variable, as Dole and Nyswander originally proposed. These factors can be understood better than before because of recent technological advances, and it is hoped that this decade will produce further clarification.

The same lifestyle changes that permit the patient to remain free from illicit drug use while on methadone maintenance are also essential for the continuing sobriety of those who taper off. Being strongly motivated and disengaging from any subculture or social group that encourages drug or alcohol use are crucial. Being involved in a social support system that actively fosters abstinence and rewards its subsequent achievements is important. This support system may include activities related to the treatment program, self-help program participation, family involvement, work or school commitments, and other social reinforcers. It is necessary to effectively address coexisting disorders, such as depression, to reduce the likelihood of relapse. Another key element is to develop healthy recreational activities, such as a passionate involvement in sports, dancing, or another physical activity, which have been a sustaining force for many.

More needs to be known about the biochemical and social characteristics of those who successfully taper off. The biochemical factors involved will hopefully be clarified by growing technological sophistication. A second area for future scrutiny is the effective treatment of coexisting disorders and how it relates to successful abstinence. A third topic to further explore is the relationship between abstaining from alcohol and remaining opioid-free.

In the interim, it is desirable to create a climate that supports a patient's decision to attempt to taper off, while also validating the choice to remain on drug replacement therapy. Consolidating lifestyle changes is key to successful tapering. The intrusiveness of methadone maintenance treatment and the stigma attached to it are further reasons to give patients such support. However, it is equally important that staff and patients alike cultivate an attitude that allows patients to continue or resume treatment with minimal loss of self-esteem. Patients often disparage major accomplishments as if these did not count because they are still on methadone. Patients as well as staff need to be educated about the rationale for

drug replacement therapy, using, for example, the parallels with insulin or thyroid replacement. It is quite likely that data supporting a disease model of opioid addiction will become available, just as for alcoholism, and will further reduce the stigma of remaining on methadone. Until then, it is important to emphasize lifestyle changes as a top priority (see ch. 11).

Staff Training

Training personnel at all levels is a key element in the effort to upgrade quality care. For example, ASAM has increasingly integrated methadone maintenance treatment into its educational offerings. It is important to develop and implement physician educational activities that foster consistency of care in accordance with rapidly evolving knowledge in the field, and systems for rapidly disseminating information about pharmacological and other advances in the field need to be improved. It should never be assumed that medical or professional credentials alone prepare a staff member to address all addiction issues or those unique to methadone maintenance treatment. Thus, training should be provided on-site and through existing vehicles in the program's home community.

Although a variety of certificate programs are available for other alcohol and drug treatment providers, rarely do these include a thoughtful presentation of methadone maintenance treatment, despite the fact that MMTPs employ large numbers of staff. Requiring methadone maintenance counselors to participate in these programs can be potentially destructive because it subjects them to the negative attitudes of the abstinence-oriented treatment providers without offering resources and practical tools for the methadone maintenance population. Before strongly encouraging practitioners to attend, programs should take care that existing educational programs do more than give lip service to the need to incorporate methadone-specific information.

Substance abuse counselors need training on how to effectively address the practical problems of the patient. Professionals brought in to address more complex psychiatric disorders need a comprehensive review of the rationale and prevailing practices in methadone maintenance treatment. While counselors in recovery have a special contribution to make, it is crucial that they not harbor negative attitudes toward remaining on methadone or assume there is only one right way to address recovery issues. Proper training is key to upgrading skills, increasing morale, and heightening understanding. Thus, it is important to include front-line staff in conferences, workshops, and on-site training efforts that build morale as well as transmit information and skills. It is also desirable to support the development of a literature that translates research developments into practical applications in the field. States may, for example, distribute newsletters and bulletins designed to keep practitioners current in their area of expertise.

Summary

This chapter has reviewed some of the major issues facing treatment providers in MMTPs. Harvesting the enormous benefits of advances in our understanding of how to improve treatment will require committing adequate resources and being willing to use our knowledge to revise policies and regulations. Accountability systems should be modernized and streamlined to provide a consistent standard of care without excessively restricting clinicians. The regulatory stance needs to be one that encourages rather than penalizes programs willing to tackle difficult clinical problems. A major training effort is needed to counteract counselor demoralization and to upgrade skills to better address counselors' myriad, complex tasks. More specialized resources, such as highly trained psychotherapists, need to be selectively used for patients with coexisting ADM disorders. Strategies for addressing continued heroin, alcohol, and other drug use should be refined. Greater efforts are needed to address the complex needs of women in treatment, particularly pregnant women, and to provide services such as child care to reduce barriers to women's extensive participation in treatment. A growing number of patients with HIV-spectrum disease need services to respond to their unique concerns; these services should be integrated into the program as a whole. Methadone maintenance treatment is relatively unique in that staff see patients regularly over a long period; support systems must be strengthened to help staff cope with the increasing number of terminally ill patients. Programs should explore ways of integrating self-help programs, with sensitivity to the complexities of this task. Patients who wish to discontinue methadone maintenance should be assisted from the perspective that their lifestyle changes are the top priority, and the issue of getting off methadone is less important than preserving those gains. Staff should be provided with training appropriate to the unique requirements of MMTPs.

A long-term plan and a secure commitment of resources are essential to achieve the goals delineated in this chapter. Although the task is great, the combination of our clinical experience and ample empirical investigation to clarify the nature of narcotic addiction and to identify

effective treatment elements give us new possibilities for achieving our goals.

Recommendations

- Review existing State regulations to determine if they actually produce their intended effect, and reduce barriers to attracting and retaining patients in treatment, e.g., child care.
- Augment resources, including technical assistance, available to MMTPs.
- Ensure that patients receive comprehensive clinical assessments and that treatment plans are individualized and contain short- and long-term goals; specify the level, duration, and frequency of counseling; and record events that trigger changes in those arrangements.
- Seek to simplify recordkeeping, decrease staff time devoted to paperwork, and improve the quality of documentation.
- Develop protocols to monitor the use of alcohol and other drugs and the productive activity of long-term patients so that these patients can be seen in a medical maintenance model; incorporate mechanisms that identify signals of potential relapse.
- Provide supplemental professional psychotherapy for patients with coexisting psychiatric disorders, coordinate drug counseling with professional psychotherapy, and ensure patient access to physicians with knowledge of appropriate prescribing practices for an addicted population.
- Provide patients with access to vocational evaluation, referral, training programs, and parenting workshops.
- Make every effort to retain patients in treatment. It is rarely appropriate to discharge patients for manifesting behaviors characteristic of addictive disorders; therefore, consider discharge only when all other alternatives have been exhausted and when it is clear that discharge constitutes the lesser harm.
- Implement activities that deemphasize the role of intoxicants (not just heroin) in patients' lives and focus on the importance of drug- and alcohol-free lifestyles in achieving positive treatment outcomes.
- Address issues that may be of particular concern to women, including intimacy, prevention of HIV and other STDs, child care, pregnancy, and family planning.
- Integrate AIDS-related activities and assistance in handling the multiple aspects of HIV-spectrum disease into methadone maintenance treatment; provide staff support and specialized recovery groups for patients affected by HIV and their families.
- Encourage patients to participate in self-help programs when appropriate for the patient and when programs are available that are hospitable to methadone-maintained patients.
- Assist those patients who wish to discontinue methadone use in addressing personality patterns, interpersonal issues, family issues, job skills, friendship patterns, health practices, recreational activities, and other issues that could lead to relapse.
- Develop and implement counselor and physician education activities and methods for disseminating information about pharmacological and other advances.

References

Regier, D.A.; Farmer, M.E.; Rae, D.S.; Locke, B.Z.; Keith, S.J.; Judd, L.L.; and Goodwin, F.K. Comorbidity of mental disorders with alcohol and other drug abuse. *Journal of the American Medical Association* 19(264):2511–2518, 1990.

Woody, G.E.; Luborsky, L.; McLellan, A.T.; O'Brien, C.P.; Beck, A.T.; Blaine, J.; Herman, I.; and Hole, A. Psychotherapy for opiate addicts. Does it help? *Archives of General Psychiatry* 40:639–645, 1983.

For Further Reading

Ball, J.D., and Ross, A. *The Effectiveness of Methadone Maintenance Treatment*. New York: Springer-Verlag, 1991.

Zweben, J.E., and Payte, J.T., eds. Opioid dependence and methadone treatment. *Journal of Psychoactive Drugs* 23(2), 1991.

Zweben, J.E., and Payte, J.T. Methadone maintenance in the treatment of opioid dependence: A current perspective. *The Western Journal of Medicine* 152(5):588–599, 1990.

Chapter 4—Admissions Policies and Procedures

John Langrod, Ph.D.

The admissions process is probably the most important stage of methadone maintenance treatment because it begins the individual's transition from street addict to methadone maintenance patient. It is the first point at which the individual is exposed to the treatment system, available services, rules, and requirements. What occurs at this stage will shape the patient's attitudes, concerns, and motivations throughout treatment. Thus, this experience must be a positive one that engages the patient, assesses major problems and needs, and lays the groundwork for ongoing clinical intervention. Therefore, it is important that MMTPs have qualified and well-trained staff and attractive physical surroundings conducive to the beginning of the treatment process, and that the evaluation of patient needs and orientation to the treatment program and services be completed efficiently and properly.

Physical Surroundings

Free-standing clinics as well as large-scale multiple-site methadone maintenance programs admit patients at the actual clinic sites. Multiple-site methadone maintenance and multi-modality treatment programs often have a central admissions process; patients are evaluated and then admitted to assigned clinics as soon as a decision to admit is made.

Physical surroundings are of utmost importance. Optimally the atmosphere should be welcoming and conducive to rehabilitation and be clearly distinct from the hostile environment in which many addicts live. Privacy is essential to convey a sense of dignity and trust between program and patients. Waiting areas should be clean, well lit, and attractively furnished. Didactic reading materials should be made available, and appropriate educational videotapes related to issues such as HIV, safer sex, substance abuse, pregnancy, parenting skills, and drug prevention can be shown to prospective patients while they are waiting. Beverages and nutritious food can be made available to patients if screening, assessment, and orientation take place over a number of hours.

Personnel

Individuals conducting admission interviews should be sensitive to human needs and familiar with programmatic regulations, policies, services, treatment issues, and other treatment resources for purposes of referral on an emergency basis. They should be culturally and gender sensitive, be bilingual where appropriate, and reflect, if possible, the demographics of the patient population being served.

The size and nature of the admissions staff should be tied to the program's structure, size, extent of services, and number of applicants to be screened. Proper staffing is essential so that a long waiting period is not an obstacle to those seeking treatment. Ideally, a fully staffed department servicing a multiple-site program should consist of a physician or physician's assistant or both, an admissions worker, and a secretary. It is often helpful for one of the staff members to be a recovering substance abuser with treatment experience. Counselors can be trained to do the admissions in single-site programs.

Requirements for Admission

Patient admission to methadone maintenance treatment must comply with Federal (21 CFR Part 291) and State requirements. To be accredited by JCAHO or CARF, programs must also comply with additional requirements. Compliance with JCAHO is particularly important when a program is part of a hospital, as noncompliance can jeopardize accreditation for the entire institution (JCAHO 1991). In general, the Federal regulations require that in order to be eligible for methadone maintenance treatment, an individual must have a documented history of a minimum of 1-year addiction to narcotics. The minimum age is 18,

but individuals between 16 and 18 may be admitted with parental consent and a documented history of two unsuccessful detoxifications. For further information, see appendix A (21 CFR Part 291).

Timely Admission and Referral

MMTPs should recognize the need to evaluate applicants on a timely basis. Trained personnel should handle promptly any inquiries regarding admissions, whether by telephone or in person, so that preliminary screening can be completed at the time of the inquiry to determine the applicant's eligibility. Applicants assessed as appropriate for methadone maintenance treatment should be offered an appointment for complete screening and assessment. Ineligible applicants should be referred to other treatment modalities.

If the MMTP is at capacity, but the applicant is eligible for admission, the admissions office should advise the applicant immediately of the existence of a waiting list and provide the applicant with one or more referrals to treatment programs that can meet the prospective patient's treatment needs, have available space, and can accommodate the patient quickly. This process can be facilitated through a central intake system. If the applicant accepts the referral, telephone contact by the admissions worker often can facilitate acceptance. If the applicant still requests program admission, even though a waiting period exists, the admissions process should be completed and the applicant's name placed on the program waiting list. Developing qualified service provider agreements or affiliations between MMTPs establishes a referral network that can be used at this critical point, thereby ensuring timely placement and possibly reducing the need for waiting lists.

It is important for MMTPs to establish criteria for identifying which patients should have priority for admission, especially when the program has reached capacity. For example, some programs offer immediate admission to pregnant women, addicted spouses of active patients, those with HIV or other serious medical conditions, and former patients who have successfully tapered off and require renewed methadone maintenance treatment.

Screening Applicants for Admission and Determining Eligibility

Screening facilitates the voluntary entry into treatment of narcotics addicts who meet current Federal, State, and program standards for admission to methadone maintenance treatment. According to Federal requirements, programs must ensure that all applicants are screened, processed, and, if they are deemed appropriate, accepted into treatment without discrimination (see Americans with Disabilities Act, 42 USC, sec. 12101 et seq.). Where applicants have special needs related to a handicap, programs must make accommodations to meet those needs, such as providing staff who communicate in sign language and making facilities accessible to those who require wheelchairs, unless the program can demonstrate that such accommodations would impose an undue burden.

Every applicant must meet minimum Federal standards for admission to methadone maintenance treatment. As part of a quality assurance effort, MMTPs should establish and regularly evaluate the criteria used to assess quality of patient care. It is important that MMTPs use existing patient assessment instruments or develop others that can provide for comprehensive treatment planning. The process should assist staff in identifying medical, mental health, legal, substance abuse, educational, vocational, financial, family, and other concerns. Many programs use the ASI for this purpose, although there are other assessment instruments that can be used. As of this writing, no patient assessment instrument has been developed specifically for MMTPs, although NIDA is evaluating the feasibility of such an instrument as part of its MTQAS initiative.

It is recommended that all program staff involved in the admissions process periodically review the requirements of State and Federal regulatory agencies.

Although many applicants lack society's documents because of their life on the street, the screening process for admission should determine the following data, which have clinical implications and are a necessary part of the admissions protocol:

- **Identity**—Identification is usually substantiated by documents such as a driver's license, birth or baptismal certificate, passport, social security card, Medicaid card, public assistance card, and/or identification card from another substance abuse treatment program.
- **Current Addiction**—To the extent possible, preliminary determination of the applicant's current degree of dependence on narcotics or opiates or both, including the route(s) of administration, and the length of time of the applicant's narcotic or opiate dependence must be completed.

The Federal standards provide exceptions to the current addiction requirement, such as for patients who have withdrawn

from methadone successfully within the past 2 years or have been released from prisons or chronic care facilities. Verification of addiction by old and new needle marks, a past treatment history, and arrest records related to drug use should be documented.

- **Age**—As noted, an applicant must be 18 or older and dependent on narcotics for a minimum of 1 year. However, if an applicant is under 18, the program must verify a minimum dependency of 2 years and two prior treatment failures and must obtain parental or legal guardian's consent.

  Persons under age 16 cannot be admitted to the MMTP unless an exemption from Federal regulations is obtained. Because the MMTP requires daily administration of an addicting medication, careful thought and consideration should be given when admitting young patients (under 18) to the MMTP.
- **Other Drug Use**—Many programs and patients feel that methadone maintenance is a specific treatment for opioid drugs. Some programs lack the skills to deal with other drug problems. However, many patients who abuse opioid drugs also abuse alcohol and other drugs. Alcohol, cocaine, and benzodiazepines are now the major drugs of abuse among methadone maintenance patients. For treatment to be comprehensive and successful, programs should detect and address these drug problems. Information should be obtained on all substances used (including alcohol and tobacco), route of use, length of time used, and amount used. Patients seriously addicted to alcohol or sedatives or both may require hospital detoxification before outpatient treatment can be initiated.
- **High-Risk Behavior**—Staff should assess the degree to which the patient engages in high-risk HIV-related behavior.
- **Past Treatment**—Information on an applicant's past treatment history, use of secondary substances while in treatment, dates and length of time in treatment, and reasons for discharge should be obtained. Consent should be obtained to secure records from these programs, when possible, to assist with treatment planning.
- **Personal Information**—Personal demographic and historical data on the applicant should be obtained, including past history and current status, including employment, educational, legal, military, family, psychiatric, and medical information.
- **Reason for Treatment**—It is important to ask the patient why treatment is sought at this time, why the program was chosen, and whether the treatment options and the nature and requirements of methadone maintenance are fully understood.
- **Urine Specimen**—Federal regulations require that a urine sample for drug screening be obtained. Urine results are expected to be positive for narcotic drugs. A specimen that is not positive does not preclude admission, but it is important to consider the reasons for a negative specimen. The screen may detect the presence of other drugs, and treatment decisions can therefore be augmented.

Medically Evaluating Patients

The initial medical screening and physical examination are critical components of treatment planning and intervention in view of the fact that narcotic addicts usually present with many medical problems and needs. While staff trained in medical aspects of narcotics addiction can complete the historical information, only a physician can make the final decision to admit the patient into treatment and to order methadone maintenance. Medical staff need to complete the following steps:

- **Determine Current Dependence**—Determine by history, examination, and screening the applicant's current degree of dependence on narcotics and, to the extent possible, the length of time the applicant has been dependent on narcotics or opiates or both. This assessment should include a physical examination for the presence of clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, and/or an eroded or perforated nasal septum and a state of sedation. The examination should evaluate the observable and reported presence of withdrawal symptoms, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea. When withdrawal symptoms are not present, some physicians have considered administering naloxone (Narcan) to induce these symptoms, thereby documenting current dependence. Many others have criticized this process as unnecessary, causing undue stress and alienating the prospective patient at this critical time.
- **Document Medical and Family History**—A complete medical history, including current information to determine chronic or acute medical conditions, such as diabetes, renal diseases, hepatitis, HIV exposure, TB, STDs, other infectious diseases, sickle-cell trait or anemia, pregnancy, and chronic

cardiopulmonary diseases should be documented. As programs develop primary care services and continue to see patients exposed to TB, HIV, and other infectious diseases, this history is critical. Any treatments the patient has had or is currently receiving for any medical condition should be documented. Patients should understand the extent of medical service offered by the program and be advised that they should disclose their methadone maintenance treatment to any physician or dentist providing care. Pregnancy, past history of pregnancy, and current involvement in prenatal care should be documented. Medical records should be sought from any health care providers upon completion of proper consent from the patient (see attachment 1).

Information on the applicant's family, including sex and date of birth of children, whether children are living with parents, and family medical and drug use histories should be documented.

- **Determine Treatment Eligibility**—The admitting physician is responsible for recommendations regarding treatment disposition and the final decision on whether the applicant is eligible and should be admitted for methadone maintenance treatment. This determination should ensure that the treatment the applicant requires is appropriate to the intensity and restrictions of that provided by the MMTP. The physician should advise the patient that the treatment prescribed can be provided on-site or by referral to a cooperating facility.
- **Explain the Process**—Treatment options should be explained to the patient, including alternatives for less intensive and restrictive treatment, other treatment options, the chances for success or failure, the benefits, and the risks. The admitting physician should inform applicants of the results of the admission evaluation and explain the treatment process. Also, the physician should explain, in easily understood language, the pharmacological properties of methadone medication. The physician who completes the admissions evaluation should determine what additional documentation is necessary to support the patient's admission, including urine toxicology results and records from other treatment programs.

For all applicants deemed eligible for methadone maintenance treatment, a comprehensive physical examination, complete laboratory workup, psychosocial assessment, preliminary treatment plan, and patient orientation should be completed during the admission process (see attachment 2 for a sample of medical tests to be completed at admission). Programs should develop procedures to ensure that all required steps are completed within regulatory time frames and are considered when developing and implementing the treatment plan. The initial methadone dosage should be ordered as soon as possible after the required admissions procedures are completed. Federal regulations require that a new patient receive an initial dose no greater than 30 mg, with a total maximum of 40 mg on the first day (21 CFR §291.505 (d)(6)(i)(A)). If higher dosages are necessary, Federal regulations require that an exemption be obtained. It is the responsibility of the physician in charge to build the patient up to an adequate dosage for maintenance treatment (see ch. 5 in this volume).

Informed Consent

An abundance of paperwork is required to admit a patient to treatment. All of the forms and consents that require the patient's signature should be explained to the patient. Some patients may be willing to sign any piece of paper in order to gain admission, but it is important that program staff not take advantage of this and that they take time to explain the forms. The patient should receive a complete and honest explanation of the necessity of each form, and the patient's rights and dignities should be preserved during this process.

In order to initiate treatment, the Federal regulations require that the patient sign an informed consent for participating in methadone maintenance (21 CFR §291.505 (d)(1)(ii)). All patients are entitled to be advised of their rights and responsibilities regarding confidentiality, program policies and procedures, and treatment services provided. (For further information about the confidentiality regulations, see 42 CFR Part 2 in appendix D.)

Programs are required to obtain consent to treatment on the FDA form (2635) designed for this purpose (Consent to Methadone Treatment; see attachment 3). This form affirms the patient's voluntary consent to receive methadone maintenance treatment. It has separate sections for female patients and those under age 18 that must be signed when relevant.

Many programs obtain other consents at this time in order to facilitate admission and improve treatment. Consent to obtain records from treatment programs or hospitals or both will allow the medical team to better assess the patient. Consent to notify a central registry (to preclude enrollment in more than one MMTP) and consent to allow the program to bill

insurers for services rendered should also be obtained.

Some MMTPs include written agreements for the patient to sign concerning program policies regarding patient fees, prevention of diversion or loitering, community incidents, proper storage of medication in the home, and other important, relevant issues. Programs should be aware that many applicants are extremely anxious during the admissions process. It may therefore be necessary to review the many forms and consents with the patient after a few weeks when he or she is more stable and able to clearly understand these documents.

Readmission

All patients seeking readmission should be entitled to the same consideration and the same rights, responsibilities, and services as newly admitted patients. Procedures for readmission should differ in ways specified by regulatory requirements and established program policies. However, for readmission, the program can review its past efforts and consider the patient's previous involvement and accomplishments in treatment, previous attendance record, reasons for previous discharge(s), prior commitment to treatment and cooperation with program policies, current needs, and length of absence from treatment. Prior to appointment or acceptance into treatment, the admissions worker should obtain and review the records from the applicant's prior treatment episodes in the program or secure relevant information from the program(s) of previous assignment or both, as needed and appropriate.

Readmission policies should be clearly stated to all patients. Some MMTPs refuse to readmit any patients discharged for rule violations, while other programs may deny readmission for a stated period.

It should be stressed that the premise of methadone maintenance treatment is that people can and do change their behavior, especially when humane, quality treatment is provided. Therefore, with few exceptions, it is not appropriate to deny readmission to patients on the basis of history or prior treatment at the program. Applicants seeking readmission should be given the benefit of the doubt and once a decision to readmit is made, staff should treat the patient as though this is a new attempt to address substance abuse, medical concerns, and social problems. Past behavior should not be held against the patient nor interfere with current treatment. At the same time, methadone maintenance treatment requires effort by both patient and staff. Patient commitment and motivation are important predictors of positive treatment outcome.

Orienting Patients Entering Treatment

Orienting patients properly is critical to fully integrating them into the treatment system. All patients should receive a thorough and easy-to-understand orientation about key aspects of treatment. Many programs summarize their treatment policies and procedures for patients and produce a patient handbook to be reviewed at home or with staff. If this is done, care must be taken to make this handbook easy to read and understand. If a language other than English is the primary language for a significant number of patients, then this handbook (and all documents that require patient signature) should be available in that language. The orientation should include an explanation of the following:

- **Goals Statement**—This is something each MMTP should develop for itself. This statement should address the program's philosophy regarding dependence on narcotics and other substances, improvement of physical and emotional health, and enhancement of the quality of the patient's life.
- **MMTP Services**—This component should describe the clinic to which the patient is assigned, the facility's location and hours of operation, what to do in the event of an emergency, and medical services provided, including required initial and annual physical examinations, urinalysis, and HIV-related services.

  Patients should be told of available and required casework and counseling services, such as substance abuse counseling, alcoholism counseling, relapse prevention techniques, family and children's services, mental health interventions, educational and vocational guidance, HIV services, counseling and health education services, legal consultation, and referrals.
- **Medication Dispensing**—This component should include information about methadone, such as methadone dosages and side effects, medication procedures, responsibility in ingesting medication, take-home policies, bottle return policies, how to request medication for travel or emergencies, security and proper storage of methadone in the home, as well as information on tapering the methadone dose when and where applicable.
- **Patient Responsibilities**—It should be made clear that patients have responsibilities when they enter treatment. Patients need to be actively involved in treatment by attending the clinic as scheduled, participating in developing their treatment plan, working toward treatment goals, meeting with

clinic medical and casework staff, and participating in groups as needed. Patients should follow established regulations. Patients should also be advised as to how to seek clarification or to discuss decisions with which they disagree.

- **Patient Rights**—Patients also have rights when they enter an MMTP. Patients have the right to treatment without discrimination, the right to be treated with dignity and respect, and the right to privacy and confidentiality in all aspects of treatment, except as allowed by law. Patients have the right to be advised of the services that are available at the program and those available by referral. Patients should know how to reach the MMTP in case of an off-hour emergency. Patients have the right to receive complete, current information about their diagnosis, their treatment plan, and the possible outcomes of treatment, as well as the right to end or refuse treatment. They are entitled to an explanation of the medical consequences of treatment decisions and have the right to a medically supervised tapering of dosage when treatment is discontinued for any reason. Patients have the right to know treatment costs and which insurance the program accepts. Patients have the right to refuse to participate in any proposed research project, the right to voice complaints without retribution, and the right to recommend changes in the services and care provided.
- **Policies and Procedures**—Patients should be told at admission that MMTPs are thoroughly regulated and monitored by Federal, State, or sometimes local agencies and, therefore, have many rules and regulations, policies, and procedures that patients need to follow. Programs should provide prospective patients with a copy of the program's rules and regulations and explain the rules and regulations as required for the patient to understand them and make an informed decision to enter treatment.

One important policy issue is the diversion of take-home doses of methadone. Some patients may sell or give away their take-home dose. Because of the seriousness of this issue and the possible consequences to nontolerant individuals, many programs have implemented policies of discharging patients from treatment if they are found diverting their medication. Whatever the consequences, programs should discuss diversion with each patient.

Another important issue to be reviewed is the MMTP policy regarding loitering and the problems and concerns this creates for good community relations. Every MMTP should have a policy and procedure to address loitering and community concerns (see ch. 12).

Admission is an excellent time to begin to describe the program's response to the HIV epidemic. Admissions staff should review basic information on HIV transmission, HIV testing, prophylactic medications, safer sex practices, condom usage, and obtaining assistance for HIV-related concerns.

The reasons for administrative discharge from treatment are also critical issues to address at this time and periodically thereafter during counseling sessions. Reasons can vary from program to program, but they usually include violence to patients or staff, disruptive behavior, threats, community incidents (loitering, diversion of methadone, sale or purchase of drugs), and other serious rule violations.

Patient orientation at admission can be performed by the admissions staff. The medical orientation should be performed by a physician, physician's assistant, or nurse.

Admissions workers can also serve as referral resources for applicants who do not qualify for admission or for whom alternative treatment may be more appropriate. Depending on their needs, patients can be referred to residential treatment, MTA, detoxification, acupuncture, or other modalities when appropriate.

Discharge From Treatment

Some patients are not able to commit themselves to the treatment process at a given time. For others, methadone maintenance treatment may no longer be appropriate or may be too limited to meet their needs. Some patients drop out prematurely, unable to accept the program's structure, while others may not yet be ready to give up alcohol and other drug use. Patients who violate cardinal rules and regulations may be too disruptive or dangerous to be in any treatment program. As was stated above, many MMTPs consider violent or threatening behavior, display of a weapon at or near a program site, verbal or physical abuse, theft or diversion of methadone, drug dealing, missed clinic visits, or fiscal noncompliance as reasons for discharge.

It is critical that programs provide patients with due process when discharge is considered and that programs develop policies and procedures to handle involuntary discharge. Some States require programs to formulate their own due process procedures. For example, New York's methadone maintenance treatment regulations require that

when a determination is made by a program to discharge a patient, the substance abuse program shall provide...

(i) a written statement setting forth the reason(s) for discharge;

(ii) written notice of his/her right to request review of the decision by the program director or his/her designee. This notice shall also contain a statement that the client may seek advice from outside resources in preparing for the program director/designee review of the discharge decision. (New York State Division of Substance Abuse Services 1990, pp. 50-51)

Treatment professionals continue to debate whether to discharge patients who are not motivated for treatment and/or who continue to abuse drugs and/or alcohol. These patients have been characterized as "not ready" for treatment, "manipulative," or "sociopathic." Some programs may discharge such patients after a standard period, while others continue to work with them in an attempt to introduce new treatment methods or to motivate them to become more involved in the program.

The issues around discharge highlight the importance of a continuum of care for methadone maintenance treatment patients. However, programs need to consider eliminating the term "termination" from the treatment vocabulary. Patients should not be discharged from all treatment possibilities; we cannot terminate methadone maintenance treatment only to expose the patient, family, and the community to resumed heroin abuse, HIV and other infections, and criminal acts to obtain money for drugs. Narcotics addiction is a chronic illness with exacerbations and remissions. Some patients simply need more time, another setting, a different approach, another modality, or renewed efforts by the MMTP to improve. We cannot "terminate" patients because they are still "sick." Rather, we should continue to explore new options for the patient, develop linkages with other modalities, and ensure continuity of care through appropriate referrals, transfer, and aftercare. When discharging a patient is necessary to protect the patients, staff, or the program's existence, it is imperative that program staff take all reasonable steps to direct the departing patient to appropriate treatment alternatives. Program staff should make every effort to find ways to help difficult patients improve their health and their lives for themselves, their family, and their community.

Summary

Admissions policies for MMTPs should ensure that patients are admitted into treatment humanely and rapidly and that program practices facilitate socializing the patient into the treatment system. Applicant screening should be extensive and thorough and should form the basis for effective, long-term treatment planning. While determining eligibility for treatment, staff should ensure that methadone maintenance is the most appropriate form of treatment, that admission is voluntary, and that the patient understands the risks, benefits, and options available. Proper patient orientation is instrumental to the therapeutic nature of the admissions process. Admissions procedures should not unduly delay the patient's admission.

Discharge from treatment should be based on sound clinical practices, with the best interests of both the patient and the program considered. Continuity of care should be considered and referral to more suitable programs should be the rule. Due process and attention to patient rights ensure that discharge practices are not abusive or arbitrary. Programs should form liaisons with other MMTPs and other treatment modalities to facilitate the continuity of care.

Recommendations

- Ensure that physical surroundings are welcoming, conducive to rehabilitation, and clearly distinct from the hostile environment in which many addicts live.
- Encourage individuals working in the admissions unit to be sensitive to patient needs and ensure that they reflect, when possible, the population being served.
- Admit patients to treatment rapidly; facilitate the socialization of the patient into the treatment system.
- Offer priority placement to pregnant women and people with serious medical and/or psychiatric problems.
- Provide thorough patient screening and assessment that forms the basis for effective treatment planning.
- Screen patients for high-risk behaviors related to HIV, STDs, MDR TB, and other infectious diseases.
- Ensure during the screening process that methadone maintenance is the most appropriate treatment modality and that treatment is not coerced.
- Provide patients with a proper orientation to the program, its policies and procedures, and patient rights and responsibilities.
- Discharge patients with considerable caution; attempt to refer patients to a more suitable treatment modality.

References

Joint Commission on Accreditation of Health Care Organizations. *Consolidated Standards Manual, 1991.* Chicago: Joint Commission on Accreditation of Health Care Organizations, 1991.

New York State Division of Substance Abuse Services. *1990 Substance Abuse Services and the Law.* Albany, NY, 1990.

For Further Reading

Ball, J.C., and Ross, A. *The Effectiveness of Methadone Maintenance Treatment.* New York: Springer-Verlag, 1991.

Cooper, J.; Altman, F.; Brown, B.S.; and Czechowicz, D., eds. *Research on the Treatment of Narcotic Addiction: State of the Art.* DHHS Pub. No. (ADM) 83-1281. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1983.

Gerstein, D.R., and Harwood, H.J., eds. *Treating Drug Problems.* Vol. 1. Washington, DC: National Academy Press, 1990.

Lowinson, J.H.; Ruiz, P.; Millman, R.; and Langrod, J. *Substance Abuse: A Comprehensive Text.* Baltimore: Williams & Wilkins, 1992.

McLellan, A.T.; Luborsky, L.; Cacciola, J. et al. New data from the addiction severity index: Reliability and validity in three centers. *Journal of Nervous and Mental Disorders* 173:412–413, 1985.

CONSENT FOR THE RELEASE OF CONFIDENTIAL INFORMATION

I, _____, authorize
(Name of Patient)

_____
(Name or general designation of program making disclosure)

to disclose to _____
(Name of person or organization to which disclosure is to be made)

the following information:

_____
(Nature of the information, as limited as possible)

_____

_____

The purpose of the disclosure authorized herein is to:

_____
(Purpose of disclosure, as specific as possible)

_____

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

_____
(Specification of the date, event, or condition upon which this consent expires)

_____

Date: _____

_____ _____

Signature of participant

Signature of parent, guardian or authorized representative when required

Attachment 2

DOCTOR'S ORDER SHEET

NAME: _____ ID #_____

DATE	ORDERED BY WHOM	MEDICATION, DIETS, LABORATORY ORDERS, ETC.	DISPOSITION ACTION	BY WHOM
		Admit to Clinic		
		BLOODWORK, INCLUDING		
		1) CBC with differential		
		2) Urinalysis		
		3) BLOOD CHEMISTRY		
		Calcium		
		Phosphorus		
		Glucose		
		BUN, Creatinine		
		Uric Acid		
		Cholesterol		
		HDL, LDL, ratio		
		Triglycerides		
		Total protein		
		Albumin, Globulin, ratio		
		Bilirubin, total		
		Alkaline Phosphatase		
		LDH, SGOT, SGPT		
		Iron		
		Sodium, Potassium		
		Chloride, CO_2		
		4) RPR (FTA p.r.n.)		
		5) Hepatitis B s Antigen		
		Hepatitis B s Antibody		
		6) TETANUS TOXOID 0.5cc I.M. stat (p.r.n.)		
		7) PPD 5 units		
		8) Others:		
		METHADONE mg daily		
		Pickup X per week		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food And Drug Administration

CONSENT TO METHADONE TREATMENT

(Provisions of this form may be modified to conform to any applicable State Law)

DATE

NAME OF PATIENT

NAME OF PRACTITIONER EXPLAINING PROCEDURES

NAME OF PROGRAM MEDICAL DIRECTOR

I hereby authorize and give my voluntary consent to the above-named Program Medical Director and/or any appropriately authorized assistants he may select, to administer or prescribe the drug methadone as an element in the treatment for my dependence on heroin or other narcotic drugs.

The procedures necessary to treat my condition have been explained to me and I understand that it will involve my taking daily dosages of methadone, or other drugs, which will help control my dependence on heroin or other narcotic drugs.

It has been explained to me that methadone is a narcotic drug which can be harmful if taken without medical supervision. I further understand that methadone is an addictive medication and may, like other drugs used in medical practice, produce adverse results. The alternative methods of treatment, the possible risks involved, and the possibilities of complications have been explained to me, but I still desire to receive methadone due to the risk of my return to the use of heroin or other drugs.

The goal of methadone treatment is total rehabilitation of the patient. Eventual withdrawal from the use of all drugs, including methadone, is an appropriate treatment goal. I realize that for some patients methadone treatment may continue for relatively long periods of time but that periodic consideration shall be given concerning my complete withdrawal from methadone use.

I understand that I may withdraw from this treatment program and discontinue the use of the drug at any time and I shall be afforded detoxification under medical supervision.

I agree that I shall inform any doctor who may treat me for any medical problem that I am enrolled in a narcotic treatment program, since the use of other drugs in conjunction with methadone may cause me harm.

I also understand that during the course of treatment, certain conditions may make it necessary to use additional or different procedures than those explained to me. I understand that these alternate procedures shall be used when in the Program Medical Director's judgment it is considered advisable.

(See reverse of this sheet for additional consent elements)

PREVIOUS EDITION IS OBSOLETE

FORM FDA 2635 (10/89)

FEMALE PATIENTS OF CHILD-BEARING AGE	PATIENTS UNDER 18 YEARS OF AGE
To the best of my knowledge, I ____ am ____ am not pregnant at this time. Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects. It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. Thus, if I am pregnant and suddenly stop taking methadone, I or the unborn child may show signs of withdrawal which may adversely affect my pregnancy or the child. I shall use no other drugs without the Medical Director or his\her assistants' approval, since these drugs, particularly, as they might interact with methadone, may harm me or my unborn child. I shall inform any other physician who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a narcotic treatment program in order that he/she may properly care for my child and me. It has been explained to me that after the birth of my child, I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following the birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the clinic's physician to know of my participation in a narcotic treatment program so that he/she may provide appropriate medical treatment for the child. All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the long term use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his/her assistants immediately if I become pregnant in the future.	The patient is a minor, _____ years of age, born _____ . The risks of the use of methadone have been explained to (me/us) and (I/we) understand that methadone is a drug on which long term studies are still being conducted and that information on its effects in adolescents is incomplete. It has been explained to (me/us) that methadone is being used in the minor's treatment only because the risk of (his/her) return to the use of heroin is sufficiently great to justify this treatment. (I/We) declare that participation in the narcotic treatment program is wholly voluntary on the part of both the parent(s)/guardian(s) and the patient and that methadone treatment may be stopped at any time on (my/our) request or that of the patient. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the treatment of an adolescent, (I/we) consent to its use upon the minor, since (I/we) realize that otherwise (he/she) shall continue to be dependent upon heroin or other narcotic drugs.

I certify that no guarantee or assurance has been made as to the results that may be obtained from methadone treatment. With full knowledge of the potential benefits and possible risks involved, I consent to methadone treatment, since I realize that I would otherwise continue to be dependent on heroin.

SIGNATURE OF PATIENT	DATE OF BIRTH	DATE
SIGNATURE OF PARENT(S) OR GUARDIAN(S)	RELATIONSHIP	DATE
SIGNATURE OF WITNESS		Date

PROHIBITION ON REDISCLOSURE OF INFORMATION CONCERNING CLIENT IN ALCOHOL OR DRUG ABUSE TREATMENT

This notice accompanies a disclosure of information concerning a client in alcohol/drug abuse treatment, made to you with the consent of such client. This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Chapter 5—Principles of Methadone Dose Determination

J. Thomas Payte, M.D.
Elizabeth T. Khuri, M.D.

The purpose of this chapter is to provide some useful clinical information pertaining to effective methadone dose determination in MMTPs.

Since the early recommendation by Dole and Nyswander (1966) of methadone maintenance doses of 80–120 mg daily, methadone dose practice has been more often determined by politics and philosophy than by rational data or good clinical judgment. There are great variations in methadone maintenance treatment practices. Studies reported by D'Aunno and Vaughn (1992) show that more than 50 percent of patients nationwide receive suboptimum methadone doses that are inadequate to prevent continued illicit narcotic use. Programs and entire States have been identified by their dose philosophy—as in "low dose" or "high dose" programs or States. Low-dose factions have often assumed an identity similar to that of a stern, caring, and conservative parent who would criticize the high-dose parent as permissive and enabling to the patient.

The evidence presented in this section clearly shows that subtherapeutic dosing practices are common among programs. Other studies have shown that adequate methadone doses, individually and clinically determined, correlate with reduced illicit drug use and improved patient retention in treatment. Perhaps the terms low dose and high dose should be discarded entirely in favor of "adequate dose." It is clear that methadone dose determination should always be a matter of good clinical judgment on the part of the experienced physician who has the advantage of having the patient in front of him or her. The establishment of therapeutic doses of methadone, as in the case of any other medication, is not a suitable matter to be decided by regulatory agencies or legislative policy.

Basic Principles

Stated in the simplest of terms, the proper dose of methadone is *enough*, that is, *enough* to produce the desired response in the patient for the desired duration of time, allowing for a margin of effectiveness and safety.

What Is the Desired Response From Methadone in Methadone Maintenance Treatment?

The following are three desired clinical effects that Kreek (1987) described as "important, separate effects" of methadone. The realization of these effects provides a reasonable clinical assurance that methadone is available at the desired receptor sites at all times, producing the "steady state" condition.

- **The prevention of the onset of opioid abstinence syndrome (AS) for 24 hours or more.** This includes the early *subjective symptoms* of withdrawal as well as the *objective signs* typical of abstinence.
- **The reduction or elimination of drug hunger or craving** that the opioid-addicted individual routinely experiences, often associated with the onset of very early subjective abstinence or in response to environmental cues or both.
- **Blockade of the euphoric effects of any illicitly self-administered narcotics.** This describes the effect of an adequate or "blockade" dose of methadone that prevents the desired sensations when heroin is injected in the usual street doses.

Kreek (1986) also emphasizes that in the tolerant individual receiving the appropriate dose, and in the absence of some factor affecting drug disposition,

- **No euphoria or other undesirable narcotic effect of any kind** can be detected by the patient or an observer.

How Much Is Enough?

The determination of dose is based on an individualized clinical process using the best professional judgment of an experienced physician with expertise in the field of addiction medicine and especially the methadone maintenance treatment modality. The decision is based on a carefully obtained history with emphasis on recent level of drug use, physical findings, knowledge of local

conditions as to relative purity of street drugs, and the observed and reported patient response to methadone at a particular dose. The majority of patients will ultimately fall into a range of effective doses. The low end of the range is thought to be about 50 mg, which is now widely accepted to be, in most cases, the lowest effective dose (GAO 1990). Optimum dose would, for most patients, be around 80 mg, plus or minus 20 mg. Some patients will do well on less than 50 mg, and others may require over 100 mg. Each case must be evaluated on an individual basis.

John Ball and Alan Ross (1991) clearly demonstrated an inverse relationship between the frequency of recent heroin use and the dose of methadone. Figure 1 is based on a study involving 407 methadone maintenance treatment patients. These data support the premise that lower doses of methadone are not as effective as higher or adequate doses in facilitating abstinence from heroin use among methadone maintenance patients.

Caplehorn and Bell from Australia (1991) demonstrated the importance of dose in retention of patients in methadone maintenance treatment. Patients at 80 mg and above were twice as likely to remain in treatment as were those at 60–79 mg, who were twice as likely to remain in treatment as were those at below 60 mg (see table 1). The importance of retention in treatment as a predictor of successful outcome of treatment will be discussed in another section.

The preceding two studies demonstrate the clear benefits of

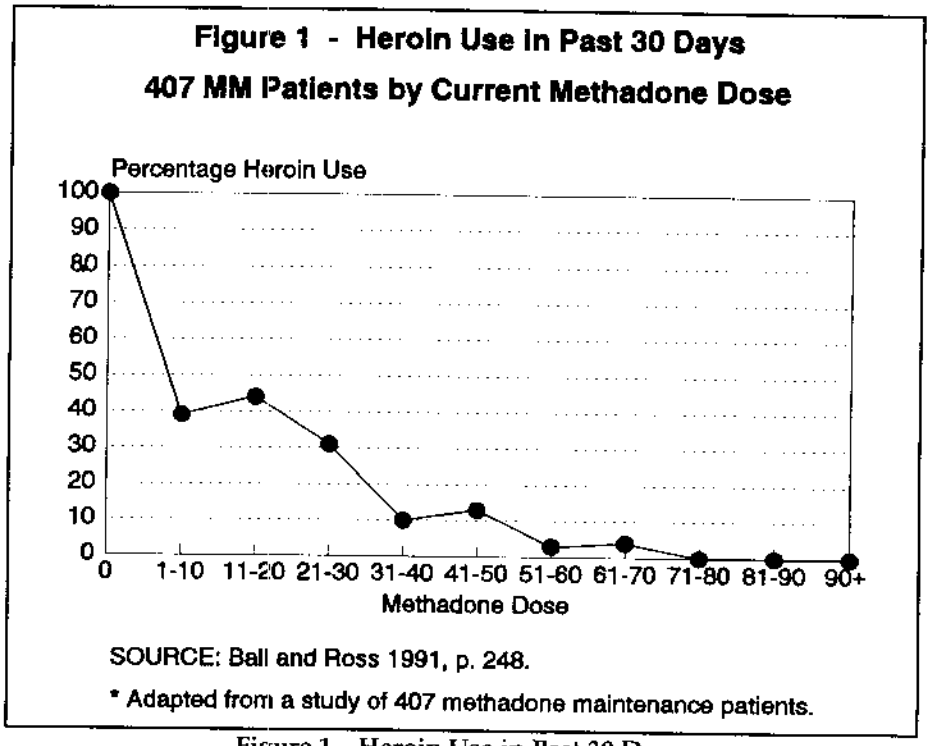


Figure 1—Heroin Use in Past 30 Days

adequate dosing in methadone maintenance treatment. In addition to facilitating abstinence and retention in treatment, the critical role of adequate methadone maintenance treatment in reducing the spread of HIV infection must be stressed. The threat of the spread of HIV makes the practice of adequate dosing in methadone maintenance treatment a matter of the highest priority. While measuring different benefits of adequate dose, it should be noted that the best treatment responses were in the 80-mg dose range and above.

Another recent study from England shows a linear relationship between methadone dose and methadone concentrations in plasma (fig. 2). Figure 2 represents an adaptation of Caplehorn and Bell's data, which were presented as a trend; the figure exaggerates the linearity to illustrate an interesting possible relationship between what may prove to be the optimum blood level and the optimum dose. Kim Wolff and colleagues (1991) have shown that mean plasma levels of methadone at the 80 mg dose are very close to 400 ng/ml, which is suggested later in this section to be an ideal range for treatment effectiveness. These data, along with an increasing number of clinical studies on three continents examining different aspects of methadone maintenance treatment, are converging toward a common conclusion relative to dosing practices in programs.

Dosing practices with methadone should not be determined by policy set at any level, whether Federal, State, or program. While the clinical scientific evidence supports adequate doses that are usually in the 80–120-mg range, the determination of an appropriate dose for the individual patient

Table 1. Relative risk of leaving treatment

Methadone doese range (mg)	Relative risk of leaving treatment (percent
Less than 60	100 (baseline)
60-70	47
80+	21

should always be an experienced physician's clinical decision.

Dosage Forms of Methadone

Methadone HCl is supplied in four dose forms for use in MMTPs:

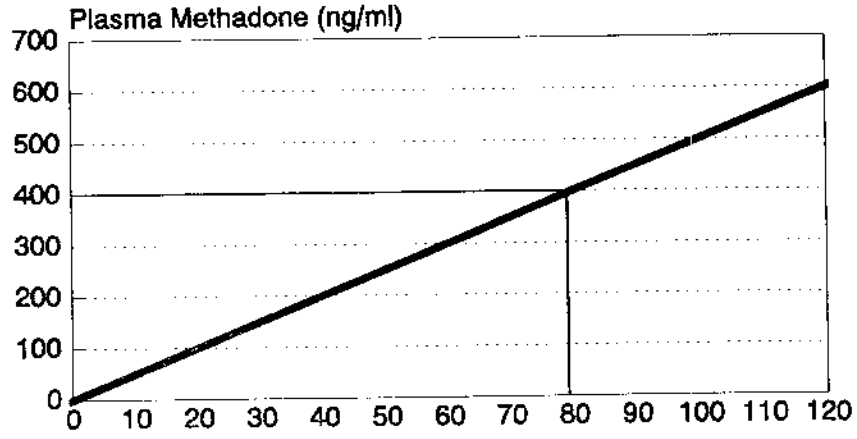
- **Disket**—A 40-mg Disket scored for 10-mg pieces is formulated with insoluble excipients to deter use by injection and breaks down quickly in water. Its advantages are easy inventory techniques and the ability to let the patients see what they are taking before water is added. It is **always** dispensed in liquid form. Its major disadvantage is that it is not suited for small dose increments and decrements.
- **Tablet**—Also available are 5- and 10-mg methadone tablets that dissolve readily in water and may be used in conjunction with the Disket to allow 2.5- to 5-mg dose changes. There is also an oral solution containing either 5 or 10 mg of methadone per 5 ml (teaspoon) and 8 percent alcohol. Because of the alcohol content and the need for larger volumes, the solutions may not be suitable for routine use in methadone maintenance programs.
- **Liquid Concentrate**—An alcohol-free liquid concentrate that provides 10 mg/ml offers complete dose flexibility, when used with a computer-assisted pump system, which provides for a very efficient methadone dispensing system.
- **Powder**—Methadone is also available as a powder for making a solution, usually of the same concentration as the liquid concentrate.

The Initial Dose and the Induction Period

The Concept

The initial dose of methadone is frequently administered to relieve a degree of AS (Martin et al. 1991). The initial dose provides a base upon which ensuing decisions are to be made during the induction to methadone maintenance. The immediate goal of methadone dosing is to relieve any signs and symptoms of AS. After full relief is established, the induction process may be continued at a slower pace in order to reach a therapeutic maintenance dose.

Figure 2 - Methadone Dose / Mean Plasma Levels



Adapted from Wolff et al. 1991

Figure 2—Methadone Dose/Mean Plasma Levels

The Details

Before the Initial Dose—Prior to the initial dose, the history and physical examination should clearly establish the existence of a **current physiologic dependence** on opioids. Exceptions to this will be discussed elsewhere but may include pregnancy or recent release from a chronic care facility.

History and physical examination should support a judgment on the part of the physician that the patient is a suitable candidate for methadone maintenance treatment and that such treatment is indicated on the basis of a thorough clinical evaluation. In keeping with sound medical practices, the physician should carefully document the basis for this decision in the clinical record.

It also may be necessary to ensure that the patient meets any admission criteria stipulated by regulations covering methadone maintenance treatment that may vary from State to State (see ch. 4, "Admissions Policies and Procedures").

The Initial Dose—The initial dose should be based on the physician's evaluation of the history and present physical condition of the patient with added knowledge of local conditions, such as the relative purity of the appropriate street drugs. The purpose of the initial and early additional doses is to relieve withdrawal and reduce or eliminate drug craving, while at the same time avoiding sedation or euphoria. There will be ample opportunity to

supplement the dose later if more methadone is needed, but it is not so easy to reduce a dose once it is administered. Thus, above all, considerations of safety should temper the physician's desire to provide relief for the addict who is suffering from AS.

Having stressed the need for individual dose determination, we will provide some specific numbers in the following section. These recommendations are made for the physician who is new to the field and who needs some guidance in early dose determination. The numbers mentioned are generally safe and conservative but are not intended to serve as rigid guidelines.

With well-established current physiologic dependence, an initial dose of 20–30 mg is usually safe. In some cases of readmission of known patients, the physician's judgment may call for initial doses slightly in excess of 30 mg. When there is any doubt as to the established degree of tolerance to opiates, initial doses of only 10 mg may be indicated. It is essential that the individual dose determination relieve withdrawal and reduce or eliminate drug craving and not induce sedation or euphoria.

The patient's history of the route of administration of narcotic drugs may also be an important determinant of response to initial dosing with methadone. Alternatives to injection of heroin include intranasal use, which consists of sniffing the dry heroin powder, which then dissolves on contact with moist nasal mucous membranes. Heroin can be smoked in the form of a cigarette laced with heroin. "Chasing the dragon" involves inhaling the vapor produced by heating heroin placed on aluminum foil. Rarely is heroin intentionally taken orally, although oral use of other opioids is common. An addiction to any narcotic used intravenously is usually more profound than addiction to a narcotic used by other routines of administration. The IDU is more tolerant to narcotics than the user who "snorts" the drug. Increasing numbers of addicts, especially in urban areas, avoid needles because of fear of HIV infection. They may have a serious and debilitating addiction to narcotics, but the method of use may be only or partially inhalation or sniffing, not the parenteral route. For example, a $100-a-day intranasal heroin habit may require initially lower induction doses than a $100-a-day IV addiction. A dosage of 20–30 mg of methadone may "hold" the patient, rather than 40–50 mg.

Table 2. The induction process

Day	Time (h)	Dose (mg)	Remarks
1	.....	20-30	Usual initial dose
1	3+	5-10	Persistent objective and subjective AS[a]
1	6+	5-10	Persistent objective and subjective AS
2	0	20 to 5-10 more than previous total	Dose adjusted up or down on the basis of response to previous day's total dose
2	3+	5-10	Persistent objective and subjective AS
3	0	20 to 5-10 more than previous total	Dose adjusted up or down on the basis of response to previous day's total dose
4-10	0	20 to 5-10 more than previous total	May be repeated on daily basis to a predetermined ceiling, at which point the physician may want direct input into further dose adjustment[b]

[a] Abstinence syndrome.
[b] Allowances must be made for time required to reach steady state level (up to 10 days).

Additional Doses in the Early Induction Phase—After oral ingestion of a dose of methadone, the maximum plasma level usually occurs at about 3–4 hours. Hence, 3–4 hours after the initial methadone dose, it would be generally safe to give a supplemental dose of methadone if signs or symptoms of AS are still present. The amount of the supplemental dose should always be determined individually but will usually be in the range of 10 mg—sometimes a little more or a little less. This process can be repeated until AS has been adequately relieved. The induction process is summarized in table 2. At this point, the dose varies with the tolerance threshold, the size of the drug habit, and the patient's mental state (e.g., fears, expectations, etc.).

Continued Induction—A review of pharmacology tells us that steady-state levels are normally achieved in four to five half-lives of any given drug. In the case of methadone, the half-life is usually over 24 hours (15–55 hours) (Baselt 1982), so we can expect at least 4–5 days to as long as 10 days to achieve steady-state maintenance. The clinical utility of this principle may help both the patient and the physician determine adequate dose. Even an adequate dose in total milligrams may not hold the patient for a full 24 hours prior to achieving the steady state. Patients can be instructed to judge their doses by how they feel in the 4–12 hour period after their dose as opposed to 24 hours later. The patient who "wakes up sick"

during early induction may just need time to achieve steady state but may be convinced he or she requires an increase in dose. Unfortunately, outpatient programs are perforce limited in their ability to meet the need for ideal multiple-dosing schedules over a 24-hour period in the first week of treatment.

During this phase of induction, the intention is to achieve an absence of withdrawal symptoms over longer durations and a growing feeling of physical and emotional well-being. If the initial stabilizing dose is subtherapeutic (below 50 mg), many clinicians will then begin a gradual escalation of dose, such as 10 mg every 7–10 days, to find the optimum level for that patient. It is important to realize that proper dose cannot be determined by purely objective means. Like pain, early AS is entirely subjective. Careful review of patient reports is essential to guide the clinician in setting dose properly. The physician should be alert to the well-practiced description of subjective AS in a patient who has pinpoint pupils, who may be scratching his or her nose, and who tends to "nod off" when thinking he or she is unobserved. The patient may be seeking a euphoric high rather than relief of withdrawal symptoms and functional normalcy.

Objective elements such as blood pressure, temperature, pulse, pupil size, tendon reflexes, fine muscle tremors, and bowel motility may be useful to the clinician in determining doses in the very early stages of treatment. However, it is the subjective symptoms, such as restlessness, irritability, sleep disorders, anxiety, depression, and drug craving, that eventually have the most utility in fine tuning methadone doses to produce optimal benefit from treatment.

The induction phase is over when the dose remains stable for more than a week and is judged to be adequate by both the physician and the patient.

The Maintenance Phase

The maintenance dose is individually determined by the experienced clinician with careful and caring attention to the essential information provided by the patient. The dose should be adequate to achieve the desired effects for 24 hours or more with an allowance for day-to-day fluctuations in absorption and elimination.

In most cases, appropriate dose levels can be adequately determined by clinical means. There are cases in which methadone blood plasma levels can be very helpful. Fortunately, reliable determination of blood plasma levels of methadone by gas-liquid chromatography is becoming more available, reliable, and affordable ($40–$60 range) (Borg et al. 1992). Increased use of this valuable clinical resource will contribute to greater individualization of care while ensuring adequacy of methadone dose.

The duration of maintenance will vary from a few months to many years. **Methadone maintenance should be continued as long as desired by the patient and as long as continuing benefit is derived from treatment.**

During the maintenance phase it is not unusual for a patient to remain on the same dose for many years. Others may require some periodic dose adjustments. Periods of increased stress, hard work, negative environmental factors, greater drug availability, and increased drug hunger may lead to the decision to increase the dose either for a temporary or an extended period. Periods of anxiety or depression, such as those precipitated by major life stressors (e.g., loss of a job, divorce, bereavement) may require appropriate methadone dose adjustments, either permanent or temporary.

Although the counseling relationship and patient interview are paramount, toxicology reports may be a useful diagnostic tool in dose determination. For individuals, especially new admissions who continue to use heroin, there should be no hesitation in adjusting the methadone to a higher and more appropriate level. It is critical that physicians recognize the relationship between inappropriate methadone dose, continuing injection drug use, and HIV infection. Methadone, effectively used, is a major weapon in deterring the spread of HIV and consequent AIDS.

When the stable maintenance patient asks that the dose be reduced, it is important that the physician thoroughly explore the motivation for the request. One patient may feel that he or she can get by on less medication; another may be responding to external pressures to "start getting off the medicine." It is not unusual for the patient to believe that those on lower doses are "better patients" than those on higher doses. Both situations require that the physician or other staff do a good job of educating patients and their significant others.

It is the opinion of the authors that methadone should always be regarded as a medication, and the dose determination as a matter for clinical judgment by the physician, in collaboration with the patient and other appropriate staff. Any dose manipulations, either up or down, as positive or negative behavioral reinforcers should be considered totally inappropriate. So-called "contingency contracting" involving medication has no place in the therapeutics of clinical medicine. An increase in methadone dose is not to be

compared with an extra serving of dessert as a reward for good behavior. This opinion is not shared by all in the field, and controversy does exist on the subject. Maxine Stitzer, for example, has done extensive work in the area of altered dose incentive procedures (1986). Another example of research on the topic of both positive and negative dose contingencies is the article by McCarthy and Borders (1985). This controversy appears to be between medical and behavioral models of addiction. On most issues, the two models are compatible or even complementary.

The phases of methadone dosing are summarized in table 3.

Table 3. Recommended dose ranges over the course of treatment[a]

Phase	Purpose	Range (comments)
Initial dose	Relieve abstinence symptoms	20-40 mg
Early induction	Reach tolerance threshold	+/- 5-10 mg (q 3-24 hours)
Late induction	Establish adequate dose (desired effects)	+/- 5-10 mg (q 5-10 days)
Maintenance	Maintain desired effects) (steady-state occupation opiate receptors)	Usually 80 +/- 20 mg (may be more than 100 mg or less than 50 mg)

[a]Proper methadone dosage should be determined on an individualized basis.

Overmedicating and Undermedicating With Methadone

The signs and symptoms associated with full withdrawal and acute opioid overdose are well known. The changes associated with overmedicating and undermedicating are less dramatic and often are subjective in nature.

The mildly to moderately overmedicated patient may show constriction of the pupils. Nodding may occur as well as some scratching of the face, especially the nose. Sedation may not be at all apparent, and, in some cases, the patients feel mildly stimulated. Nausea may be a complaint, particularly in the newer patients. At a fixed dose, these effects tend to pass as tolerance is developed. When overmedication is detected or suspected, a reduction in the dose is indicated along with careful explanation to the patient, except in cases using "blind dosing" techniques.

The minimally or very mildly overmedicated patient may pose a greater problem. During the time that the patient experiences effects of a dose slightly in excess of the established tolerance threshold, there is a definite but mild sense of well-being. Energy and motivation levels are increased so that the individual may want to clean house or wax the car, for example. What is important is that the individual not attribute this feeling to the drug, as was the case during the "high" or nodding phase. The addict may associate this state with being "normal"; hence the term *"addict's abnormal normality."* This state is experienced after a euphorigenic dose of heroin or methadone. It lasts much longer with methadone.

As the effect wears off, the exaggerated sense of well-being, motivation, and energy are no longer present. This state is in reality the addict or patient's "normal" state, which can be described as a full awareness of one's internal and external environment. This individual, who is just now feeling normal, is convinced that he or she is starting to "get sick."

As further tolerance develops, the abnormal normality is no longer experienced, and the patient complains that the dose is no longer holding and that an increase in methadone dose is needed. If a dose increase is granted, there is a brief return to this condition that the patient thinks is normal. The return is brief in that it depends on a dose in excess of the established threshold, which will further raise the tolerance threshold to the new dose level. When that happens, the patient is back again wanting more methadone.

It is important for the physician and other staff to be aware of this phenomenon. By carefully explaining it to the patient with reference to the patient's own experience with heroin, patients can learn to recognize the problem and facilitate stabilization.

The underdosed patient is easy to detect if the pupils are dilated and yawning, sniffles, lacrimation, and chills are noted. The undermedicated patient relates the presence of anxiety, insomnia, drug hunger, and drug-seeking behavior. Hence, it is not possible to rely on purely objective means as a basis for a dose increase.

When the Dose Is Not "Holding" the Patient

A variety of complaints may introduce the case for more methadone, for example, "I wake up sick; I have a strong urge to fix; I am fixing." There are a number of reasons why the patient who was stable may be having problems in relation to dose.

Perhaps the most frequent cause is the ingestion of other substances, especially alcohol. Any drug that stimulates the liver's microsomal enzyme-oxidizing system may accelerate the metabolism of methadone. Barbiturates and other sedative-hypnotics may also produce this effect.

Specific drugs known to accelerate methadone metabolism, and at times, to precipitate AS, include rifampin (Tong et al. 1981), phenytoin (Dilantin) (Kreek 1978), and carbamazepine (Tegretol) (see table 4). A.J. Saxon (1989) suggested that valproic acid, unlike other anticonvulsants, has no effect on methadone metabolism. Although this opinion was based on only two cases, consideration of valproic acid would be justified when the clinician faces a choice between seizures or abstinence.

Inadvertent administration of opioid agonist/antagonist drugs can also precipitate AS by an entirely different mechanism (see table 4).

Environmental changes and other stresses can cause the patient to perceive that the dose is not adequate and to experience increased drug craving. Events that increase the availability of drugs, such as another addict moving in at home or a "connection" opening nearby, can intensify craving. Dose increases may be quite appropriate in such cases, although efforts should focus on resolving the offending situation rather than relying on more methadone. Conversely, diminished availability of drugs, as may occur in prison or jail, may diminish drug craving.

Table 4. Some specific drugs known to accelerate methadone metabolism

Drug	Mechanism	Effect (remark)	Reference
Rifampin	Induction MEOS[a] in liver	AS[b]	Kreek et al. 1976
Phenytoin	MEOS	AS	Tong et al. 1981
Ethyl alcohol	MEOS	Potentiation, then AS	Kreek 1981
Barbiturates[c]	MEOS	AS	Liu and Wang 1984
Carbamazepine	MEOS	AS	Kuhn, Halikas, and Kemp 1989; Payte 1992
Opiod agonist/ antagonists	Opioids displaced from receptors	AS (usually inadvertent)	Zweben and Payte 1990

[a] Microsomal enzyme-oxidizing system.
[b] Abstinence syndrome.
[c] Human reports are inconsistent.

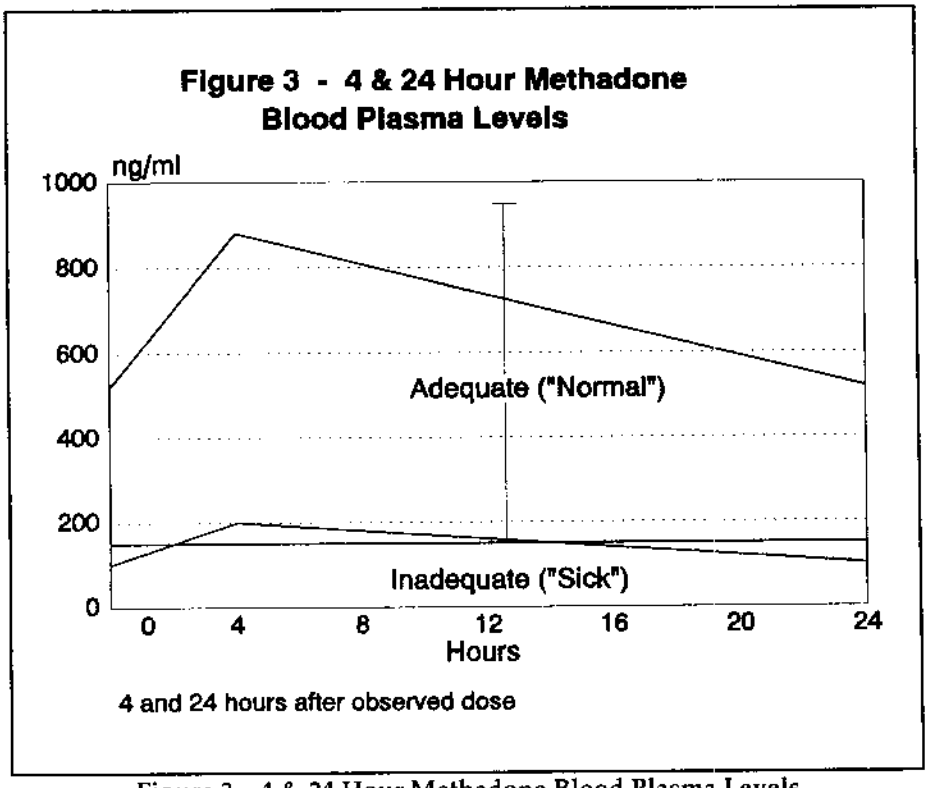


Figure 3—4 & 24 Hour Methadone Blood Plasma Levels

In the absence of medication or environmental contributions and polysubstance abuse in an apparently destabilized methadone maintenance patient, plasma level determinations should be considered. Figure 3 is an approximation of a typical 24-hour blood plasma curve based on established steady-state maintenance, with the zero-hour dose approximately 24 hours after the previous dose. The data for the figure are derived by averaging a series by Inturrisi and Verebey (1972) and one by Kreek (1973). Both series clearly demonstrated that the peak level is less than twice the trough level. This ratio is important for the clinician who is interpreting methadone blood plasma levels.

At present, 150 ng/ml is generally accepted as the lowest level that will maintain steady-state effect (Dole 1988). The optimum 24-hour mean plasma level may be more in the 400-ng/ml range (Goldstein pers. com. 1991; Kreek 1973; Tennant 1987; Wolff et al. 1991). Loimer and colleagues (1991) suggest that "methadone plasma concentrations of 400 ng/ml are necessary to suppress any further opiate action and to provide stabilized maintenance." The optimum dose is the level at which there is adequate methadone to

provide constant availability to the opiate receptors. The data for the lower curve in figure 3 are based on experience with an actual patient on 80 mg of methadone daily who persistently complained of waking up sick and having drug hunger. This patient responded to an increase in dose.

Figure 4 illustrates experience with a patient with low zero- and 24-hour methadone plasma levels with a peak that was within normal values but was high in relation to the very low trough levels. In the figure, the peak is more than three times the nadir and the absorption and elimination portions of the curve are much steeper, indicating a rapid change in state. In such a clinical situation, it is likely that the rate of change is as important as, or more important than, the numeric values themselves (see fig. 4).

If the dose is increased in an effort to bring up the 0–24-hour level, the peak level may be excessive, thus exaggerating the abnormal curve. Assuming that the cause for the rapid elimination is not apparent (drugs, urinary pH, etc.), a "split dose" may be indicated to avoid having the patient somewhat overmedicated for a few hours, feeling normal for a while, and still feeling bad or waking up sick later. Figure 4 shows the split-dose desired responses in two so-called "fast metabolizers." In both cases, the total dose is the same as for a 24-hour period and the area under the curve is essentially unchanged. What changes is that both the low nadir and the high peak are eliminated, resulting in a smoother clinical response associated with the flattening of the curve.

Excretion of methadone via the kidneys is pH dependent. Studies have shown that by altering the pH from very acid to very alkaline, the half-life of methadone may vary from less than 18 hours to greater than 40 hours (Nilsson et al. 1982). The clinical significance of more modest variation in urinary pH has not been demonstrated but probably deserves attention in evaluating the patient who is not getting a 24-hour effect from the methadone.

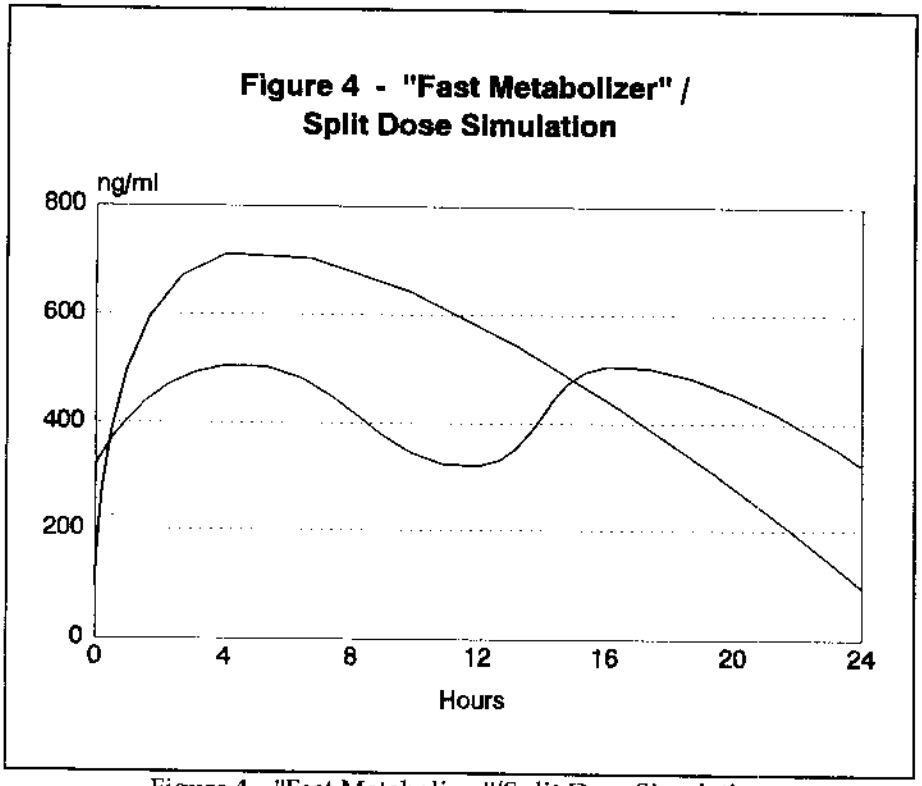


Figure 4—"Fast Metabolizer"/Split Dose Simulation

Pain Management in Methadone Maintenance Treatment

Acute Pain

Methadone-maintained patients occasionally require medical, surgical, and dental procedures that are provided or performed away from the methadone maintenance program. When the conditions or procedures cause pain, serious errors in patient management commonly occur. As a result, pain is either not treated or seriously undertreated.

The practitioner often believes that a patient taking 80 mg of methadone daily could not possibly need anything else for pain. This is absolutely incorrect. It should be crystal clear that the methadone-maintained patient is fully tolerant to the maintenance dose of methadone and thus experiences no analgesic effect from this narcotic at the stable dose.

Another common clinical error is based on the belief that any exposure to opioid agonist analgesics will somehow aggravate the addictive disorder. There is some basis for this belief, in that relapse to illicit opioid self-administration has occurred when former heroin addicts, in remission or recovery, have been given narcotics. In the authors' experience, these situations most often occur when the prescribing practitioner is unaware of the history of opioid dependence and the patient takes an active role in seeking narcotics, *justified* by the temporary pain condition. In 1980, Kantor and coworkers compared a group of methadone maintenance patients who were exposed to

significant amounts of narcotic analgesics in the course of hospital treatment with a group of methadone maintenance patients with no such exposure. The patients were followed for a mean of 20 months, with the narcotic-exposed group showing no differences to controls.

The inadequate treatment of pain in methadone-maintained patients commonly leads to disruptive behavior by angry and frightened patients and discharge against medical advice, often to the detriment of the patient's health (Zweben and Payte 1990).

The principles of managing acute severe pain in the methadone-maintained patient are quite simple:

- Do not interrupt daily methadone maintenance.
- The patient's dose should not be changed, whether by oral or intramuscular routes, although it may be divided: 50 percent of usual dose before and 50 percent after surgery, intramuscularly administered.
- Discuss pain management with the patient and give assurances that he or she will be afforded adequate relief.
- When nonnarcotic analgesia is not effective, short-acting opioid agonist drugs should be used in higher and more frequent doses against the background of continued methadone maintenance.
- Do not use agonist/antagonist drugs such as pentazocine (Talwin), butorphanol tartrate (Stadol), nalbuphine hydrochloride (Nubain), and buprenorphine (Buprenex). These agents may precipitate AS in the methadone-maintained patient.
- Change to nonnarcotic agents as soon as practical.
- Avoid prescribing for self-administration.

Patients may request a temporary increase in methadone dose during an episode of pain. This practice is not uncommon. However, increasing the daily methadone dose may afford only approximately 6 hours of analgesia. Short-acting opioid analgesics are appropriate and effective in methadone maintenance treatment patients if used properly. Because of the established cross-tolerance, the short-acting opioid agonist agents may require larger-than-usual doses and more frequent administration. Attending physicians may need both firm guidance and reassurance from experienced addiction medicine professionals because the attending physicians are not accustomed to using such large narcotic doses. Still others may become judgmental, angry and punitive and withhold medication. Many unpleasant situations and much unnecessary suffering can be avoided by discussing pain management plans with both patient and physician *before* surgery whenever possible.

Chronic (Benign) Pain

Chronic pain, by itself, is among the most difficult clinical problems seen in medical practice. *Primary* chronic opioid dependence (as opposed to iatrogenic drug dependence *secondary* to the chronic pain disorder) seen in combination with chronic pain is especially problematic.

A referral to a professionally recognized Comprehensive Pain Center is usually appropriate. The methadone-maintained chronic pain patient is a suitable candidate for most techniques employed in such centers, such as neuroablative procedures, biofeedback, acupuncture, psychotherapy, behavioral management, and other procedures. A common problem in such referrals is the insistence of the expert on pain management to withdraw the patient from methadone. This is rarely appropriate and will often result in a failure of both the treatment of the addiction and the pain disorder. To be effective, the pain management expert and the addictionologist should coordinate treatment in an extended team approach.

The chronic pain patients seen in methadone maintenance treatment programs have often failed at one or more pain clinic treatments, have had multiple useless surgical procedures, are suffering from serious chronic depression, and have escalated drug use significantly.

Many of these dual-diagnosis patients have a level of chronic pain, with episodes of more acute severe pain. Surprising as it may seem, the authors have experience suggesting that at least some chronic pain patients benefit from long-term adequate-dose methadone maintenance with episodic use of short-acting opioid analgesics during episodes of acute pain. Careful supervision and monitoring is essential. Medications are not provided to be on hand in the event pain occurs. However, provisions must be made to be able to respond promptly to the episodes of acute pain.

As in the management of acute pain, when opioids are used, both the dosage and the frequency of administration should be increased in order to provide adequate relief.

For many such patients, there are no really satisfactory answers and treatment is reduced to a process of containment and damage control. Support, reassurance, and compassion are the most essential features in managing the patient with chronic pain.

Dosage Reduction Techniques

Despite the effectiveness of long-term methadone maintenance treatment, there are situations in which, for a variety of reasons, the

patient may wish to attempt a dose reduction as a means of eventually becoming abstinent. Staff and patients should be aware of the inherent risks associated with relapse to injecting drug use. Ideally, withdrawal should be attempted only when strongly desired by the rehabilitated patient. However, it is recognized that there is occasionally a need for dose tapering for administrative reasons, such as extreme antisocial behavior or noncompliance with minimal program standards. This step should be taken rarely and judiciously. Ball (1988) reported 82.1 percent relapse to injecting heroin use within 12 months following withdrawal from methadone. Patients should be monitored closely; in the event of a relapse or an impending relapse, additional therapeutic measures should be used, including rapid resumption of methadone maintenance treatment when appropriate (ASAM 1991).

Relapse prevention techniques should be incorporated into counseling and program elements both prior to and during dose reduction. Such structured techniques may be useful as safeguards, both in preventing and preparing for relapse. Use of self-help techniques is highly recommended, especially during a dose reduction period.

Although there is no reference in the methadone literature that would indicate that the rate or method of withdrawal influences the postwithdrawal prognosis in terms of the ability to remain abstinent, an appropriate and usually slow dose reduction should be prescribed for humane reasons. Such a deliberate pace provides a greater opportunity for patients to change their minds and resume methadone maintenance treatment before relapse occurs.

Blind-dose reductions offer advantages and are preferred by many patients and clinicians. Such a procedure should be discussed and agreed on before the withdrawal from methadone begins. It is not appropriate to withdraw a patient from methadone maintenance without his or her knowledge and consent. Nonconsensual blind withdrawal is not acceptable from either a clinical or an ethical point of view.

The technique and rate of graded reduction will vary widely among patients. The authors have had extensive experience in withdrawing patients from methadone and suggest that dose reductions be less than 10 percent of established tolerance or maintenance dose and that there be 10–14 day intervals between dose reductions. As the reductions get smaller and the intervals remain the same, it is easy to see that many months to a year or more can be spent in such a graded reduction. The rate of withdrawal can be increased or decreased on the basis of the response of the individual patient.

Regardless of rate of withdrawal, a point will be reached at which the steady-state perfusion of the opiate receptors is no longer complete and drug hunger and craving may recur. This point may occur at any dose but is commonly encountered between a 15- and 40-mg daily dose of methadone. Some highly motivated patients who have a good support system may be able to continue the withdrawal schedule. The authors have often observed that many patients appear to have a specific and individual methadone threshold. This threshold is a point at which further reductions in dose are very difficult and the patient becomes highly symptomatic, often resorting to other drugs or alcohol to relieve the distress.

The physician and staff should be alert to substitution of other substances, such as alcohol, cocaine, sedative-hypnotics, or other nonopioid substances, during dose reduction. The "substitute addiction" is often more devastating than the heroin addiction and is not a wise exchange for the entirely safe, extended methadone maintenance treatment.

Many clinicians have some success with withdrawal procedures using clonidine and, in some cases, naloxone (Narcan) or naltrexone hydrochloride (Trexan) or both. It is beyond the scope of this paper to discuss these techniques.

Summary

Proper determination of methadone dose for patients in methadone maintenance treatment should be individualized and arrived at by an experienced physician who carefully evaluates the subjective and objective data. The optimum methadone dosage for most patients is from 80 mg to 120 mg. Adequacy of dose is the goal, and high-dose/low-dose philosophies are irrelevant. Cessation of all illicit and inappropriate use of narcotics is the major objective of methadone maintenance treatment, with special emphasis on injection narcotic use. It is important that both physicians and program staff be educated regarding the importance of adequate dosage. It is hoped that in the near future affordable and reliable methadone plasma or serum level determinations will be widely available and provide for pharmacokinetically based dose regimens to ensure effectiveness of methadone maintenance treatment.

Recommendations

- Determine methadone dose on the basis of good clinical judgment by an experienced physician who has examined the patient; dose is not a suitable matter to be decided by regulatory agencies or legislative policy.

- Provide methadone doses that are enough to produce the desired response in the patient for the desired duration of time, with an allowance for a margin of effectiveness and safety. The majority of patients will ultimately fall into a range of effective doses, with the low end of the range being about 50 mg and the high end about 120 mg; for most patients, the effective dose is likely to be about 80 mg, plus or minus 20 mg.
- Ensure that history and physical examination support a judgment on the part of the physician that the patient is a suitable candidate for methadone maintenance treatment.
- Base the initial dose on the physician's evaluation of the history and present condition of the patient, with added knowledge of local conditions, such as the relative purity of the available street drugs.
- Determine the maintenance dose individually, with careful and caring attention to the essential information provided by the patient; the dose should be determined by an experienced physician and should be adequate to achieve the desired effects for 24 hours or more with an allowance for day-to-day fluctuations and elimination.
- Continue methadone maintenance as long as desired by the patient and as long as benefit is derived from treatment.
- Avoid manipulating doses either up or down to reinforce positive behavior or punish negative behavior.
- Manage pain by the use of selected short-acting opioid agonist drugs; relief can often be attained by using higher doses at more frequent intervals.
- Attempt withdrawal only when strongly desired by the rehabilitated patient.

References

American Society of Addiction Medicine. *American Society of Addiction Medicine Policy Statement on Methadone Treatment*. Washington, DC: American Society of Addiction Medicine, 1991.

Ball, J.C. Reducing the risk of AIDS through methadone maintenance treatment. *Journal of Health and Social Behavior* 29(September): 214–226, 1988.

Ball, J.C., and Ross, A. *The Effectiveness of Methadone Maintenance Treatment*. New York: Springer-Verlag, 1991.

Baselt, R.C. *Disposition of Toxic Drugs and Chemicals in Man*. Davis, CA: Biomedical Publications, 1982.

Borg, L.; Ho, A.; and Kreek, M.J. Correlation of methadone blood levels from three laboratories with dosage and abstinence symptoms: A pilot study. In: *Problems of Drug Dependence 1992: 54th Annual Scientific Meeting*. Keystone, CO: Committee on Problems of Drug Dependence, Inc., June 1992.

Caplehorn, J.R.M., and Bell, J. Methadone dosage and retention of patients in maintenance treatment. *The Medical Journal of Australia* 154:195–199, 1991.

Cooper, J.R. Ineffective use of psychoactive drugs—methadone treatment is no exception. *Journal of the American Medical Association* 267(2):281–282, 1992.

D'Aunno, T., and Vaughn, T.E. Variations in methadone treatment practices result from a national study. *Journal of the American Medical Association* 267(2):253–258, 1992.

Dole, V.P. Implications of methadone maintenance for theories of narcotic addiction. *Journal of the American Medical Association* 260:3025–3029, 1988.

Dole, V.P., and Nyswander, M.E. Rehabilitation of heroin addicts after blockade with methadone. *New York State Journal of Medicine* 66(15):2011–2017, 1966.

General Accounting Office. *Methadone Maintenance: Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed*. GAO/HRD-90-104, 1990.

Inturrisi, C.E., and Verebey, K. The levels of methadone in the plasma in methadone maintenance. *Clinical Pharmacology and Therapeutics* 13:633–637, 1972.

Kantor, T.G.; Cantor, R; and Tom, E. A study of hospitalized surgical patients on methadone maintenance. *Drug & Alcohol Dependence* 6:163–173, 1980.

Kreek, M.J. Plasma and urine levels of methadone. *New York State Journal of Medicine* 73(23): 2773–2777, 1973.

Kreek, M.J. Drug interactions with methadone. *Annals of the New York Academy of Sciences* 281:350–371, 1976.

Kreek, M.J. Medical complications in methadone patients. *Annals of the New York Academy of Sciences* 311:110–134, 1978.

Kreek, M.J. Medical management of methadone-maintained patients. In: Lowinson, J.H., and Ruiz, P., eds. *Substance Abuse: Clinical Problems and Perspectives*. Baltimore: Williams & Wilkins, 1981, pp. 660–670.

Kreek, M.J. Tolerance and dependence: Implications for the pharmacological treatment of addiction. In: Harris, L.S., ed. *Problems of Drug Dependence, 1986*. National Institute on Drug Abuse Research Monograph 76. Rockville, MD: National Institute on Drug Abuse, 1986.

Kreek, M.J. Opiate-ethanol interactions: Implications for the biological basis and treatment of combined addictive diseases. In: Harris, L.S., ed. *Problems of Drug*

Dependence. National Institute on Drug Abuse Research Monograph 81. Rockville, MD: National Institute on Drug Abuse, 1987.

Kuhn, K.L.; Halikas, J.A.; and Kemp, K.D. Carbamazepine treatment of cocaine dependence in methadone maintenance patients with dual opiate-cocaine addiction. In: Harris, L.S., ed. *Problems of Drug Dependence.* National Institute on Drug Abuse Research Monograph 95. Rockville, MD: National Institute on Drug Abuse, 1989.

Loimer, N.; Schmid, R.; Grunberger, J.; Jagsch, R.; Linzmayer, L.; and Presslich, O. Psychophysiological reactions in methadone maintenance patients do not correlate with methadone plasma levels. *Psychopharmacology (Berl)* 103(4):538–540, 1991.

Martin, J.; Payte, J.T.; and Zweben, J.E. Methadone maintenance treatment: A primer for physicians. *Journal of Psychoactive Drugs* 23(2):165–176, 1991.

McCarthy, J.J., and Borders, O.T. Limit setting on drug abuse in methadone maintenance patients. *American Journal of Psychiatry* 142(12):1419–1423, 1985.

Nilsson, M.I.; Widerlov, E.; Meresaar, U.; and Anggard, E. Effect of urinary pH on the disposition of methadone in man. *European Journal of Clinical Pharmacology* 22:337–342, 1982.

Payte, J.T. A patient on carbamazepine 800 mg daily and methadone 180 mg. Blood plasma levels at 3 hours 118 ng/ml and less than 25 ng/ml at 24 hours. Unpublished data.

Stitzer, M.L.; Bickel, W.K.; and Bigelow, G.E. Altered dose incentive procedures: Effects on polydrug use among methadone maintenance patients. In: Harris, L.S., ed. *Problems of Drug Dependence, 1986.* National Institute on Drug Abuse Research Monograph 76. Rockville, MD: National Institute on Drug Abuse, 1986.

Tong, T.G.; Pond, S.M.; Kreek, M.J.; Jaffery, N.F.; and Benowitz, N.L. Phenytoin-induced methadone withdrawal. *Annals of Internal Medicine* 94(3):349–351, 1981.

Wolff, K.; Sanderson, M.; Hay, A.W.M.; and Ralstrick, D. Methadone concentrations in plasma and their relationship to drug dosage. *Clinical Chemistry* 37(2):205–209, 1991.

Zweben, J.E., and Payte, J.T. Methadone maintenance in the treatment of opioid dependence: A current perspective. *Western Journal of Medicine* 152(5): 588–599, 1990.

Chapter 6—Urinalysis as a Clinical Tool

Ira J. Marion, M.A.

The screening of urine specimens for the presence of methadone and drugs of abuse has been an integral part of MMTPs since they first began. The developers of methadone maintenance treatment, Drs. Vincent P. Dole and Marie E. Nyswander, instituted laboratory analysis to provide an objective measure of program efficacy to the scientific community and to provide a clinical tool for practitioners to use with patients as they progressed toward established goals. Yet nowhere does a protocol or "manual" exist for clinicians, administrators, or SSAs to aid understanding of the relationship of urine surveillance to the MMTP. This lack exists despite increasing concerns about the need for diligence relative to urine screening, about patient diversion of take-home supplies of methadone, and about patients who continue to abuse drugs and alcohol while in treatment.

The Regulatory Basis for Urinalysis

Since 1972, urine screening has been a required procedure in methadone maintenance treatment in the United States and elsewhere, although the requirements related to this process have been modified over the years. The FDA has the regulatory authority and responsibility for monitoring methadone maintenance treatment programs, in consultation with NIDA. Currently, regulations promulgated by FDA and NIDA (21 CFR Part 291) require an admission urinalysis and eight random urine specimens for the presence of methadone and drugs of abuse during the first year of treatment. In subsequent years, at least quarterly urinalyses are required, except for those patients who receive a 6-day supply of take-home medication; those patients must have their urine taken and screened at least monthly. The Federal regulation requires that urine specimens be "collected in a manner that minimizes falsification" (21 CFR §291.505(d)(2)) and that each urine be tested or analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates, as well as any drug(s) that have been determined by the program to be abused in that particular locality. Further, the regulation requires that programs use a laboratory that complies with all applicable Federal proficiency standards, as well as any State requirements. Any change of laboratory by a program must be approved by the FDA. Finally, the Federal regulations require the program director to ensure that urine screening results are not used solely to force a patient out of treatment, but rather as a guide to modify treatment approaches. The director must ensure that when test results are used to change treatment status, *presumptive* results are distinguished from *definitive* results.

These are minimal standards for urinalysis. States may develop methadone maintenance treatment standards and regulations that can exceed Federal requirements; programs must adhere to the more stringent regulation, whether Federal or State. In the matter of urine surveillance, some States require more frequent testing than does the Federal government. For example, in New York State, where approximately 35,000 patients are in methadone maintenance treatment, the Office of Alcoholism and Substance Abuse Services (formerly the Division of Substance Abuse Services) requires that "Urine drug screening for all new patients accepted for treatment shall be conducted weekly for the first 3 months in treatment. Patients who complete 3 months of urine drug screening showing no indications of substance abuse may be placed on a monthly urine schedule" (New York State Division of Substance Abuse Services 1990, p.94). Further, New York's regulation requires that patients who test positive for drugs other than methadone should be returned to a weekly urine screening schedule.

The regulatory framework for urine screening in methadone maintenance treatment differs from State to State. Some States have no specific requirements, so the Federal regulations are the only standard for these programs;

however, Federal urinalysis requirements should be seen as minimal and regulatory in nature. Programs should evaluate their clinical needs and develop policies and procedures to integrate urinalysis into treatment planning and clinical practice.

From time to time, the U.S. Public Health Service convenes an interagency Methadone Policy Review Board consisting of representatives of the Federal agencies involved in the provision, regulation, or quality of methadone maintenance treatment services. The Board has representatives from FDA, NIDA, CSAT, DEA, ONDCP, and the VA. This Board has been concerned about urinalysis issues, particularly the continuation of patient take-home supplies when urinalysis reports are positive for drugs of abuse or negative for methadone.

Techniques and Methods

Since the inception of methadone maintenance treatment, the technology employed to provide laboratory analysis of urine specimens has developed and improved as the practice of drug testing has become widespread. In the last decade, public concern for drug use in the workplace and for drug use in collegiate and professional sports has resulted in dramatic increases in drug-testing programs. The implications of this testing are widespread, with reputations and careers always at stake (Coffman and Fernandez 1991). Therefore, the techniques employed in obtaining urine specimens and the accuracy and validity of testing methods are critical (Schwartz et al. 1991). Usually, sophisticated and expensive laboratory methodologies such as radio-immunoassay (RIA) and gas chromatography/mass spectrometry (GC/MS) are employed when the test result will be used to decide employment, participation in a major league competition, or the ability to practice law or medicine. The initial test result is generally validated by a second confirmatory test using a different, more sensitive test procedure. These methods allow the laboratory to verify positive or negative findings with specificity. In most cases, urine is obtained under direct observation and a chain of custody of the specimen is maintained to ensure that the tested specimen can be traced to the person to whom it belongs, that the results are quantitatively and qualitatively accurate, and that the results will stand up in a court of law.

It is critical to distinguish between these methods and those commonly used in methadone maintenance treatment programs. Generally, MMTPs employ collection and laboratory methods that provide routine urine *screening*, while the sophisticated collection and methodology described above are more aptly characterized as *testing*. The distinction between screening and testing is important in examining urinalysis in methadone maintenance treatment.

In most well-run MTTPs, urine is collected on a frequent and routine basis although not necessarily under direct observation. Rather, these urine specimens are obtained randomly from patients, who must provide them upon request. Depending on the treatment setting and the size of the program, most clinics assign a staff member the responsibility of greeting the patient and determining if a urine specimen is required on that particular visit, prior to the patient's receiving his or her medication. This determination may be made on the basis of a computer-generated random list or treatment decisions by clinical staff. The patient is sent to the bathroom to provide the specimen in a labelled container. Most programs monitor the bathroom to ensure that only one patient uses it at a time and that the patient does not bring packages or parcels into the bathroom. The person collecting the urine specimen checks the container to determine if it is a "fresh" urine. The specimen is then packaged and sent to the program laboratory for screening.

Most MMTPs, because of the volume and cost of urine surveillance, use thin-layer chromatography (TLC) or enzyme immunoassay (EIA) laboratory testing methods in conducting required urine screening. TLC is one of the oldest methods and is still utilized as a practical technique for comprehensive drug screening. A screen based on TLC techniques can detect amphetamines, benzodiazepines, barbiturates, methadone, propoxyphene, tricyclic antidepressants, and nicotine. The most frequently used EIA method in this country is the EMIT system, which allows for short analysis time, can be automated for large-scale samples, and can be used on-site by small programs (Hawks 1986; Manno 1986).

These efficient, low-cost screening methods each have benefits and limitations. EIA provides a testing threshold that allows detection of extremely small quantities of abused substances but does not have the specificity to determine which drug in a class is present (Daistha and Tadrus 1975; Saxon et al. 1990). For example, this method can detect the presence of opiates but cannot distinguish between morphine (the metabolite of heroin excreted in urine), codeine, and other opiates, including poppy seeds commonly used in baked goods. TLC can make these distinctions but can also produce false negative reports because it requires relatively larger

amounts of abused drugs to be detected in the urine.

However, neither the TLC nor the EIA method can be referred to as urine *testing* because an isolated result, with or without confirmatory testing, cannot be presented in a court of law and certified as accurate. These are urine *screens*, which, in the context of regular, routine, and random surveillance, can yield a patient profile to be used in treatment planning, counseling, casework, and determining the adequacy of the patient's methadone dosage, particularly as patterns emerge during treatment.

It is important for practitioners and State and Federal regulators to understand the limitations of the urine screening methods used in the majority of methadone maintenance treatment programs (Morgan 1984). This knowledge may enhance the treatment process and ameliorate some of the regulatory concerns and issues that face methadone maintenance treatment providers.

Urine Screening Procedures

Urine screening is an important component of methadone maintenance treatment. The results can be used as valuable tools for both clinicians and administrators. Yet, the process of obtaining urine specimens and using them in the treatment process is often confusing to patients, counselors, physicians, and other staff who must consider the results in conferring privileges and in making decisions about dosage and take-home medication.

Ideally, the clinical setting in which urine specimens are obtained, and the results presented and used in treatment planning, can enhance the treatment process, even when privileges must be based on a pattern of urine results. Methadone maintenance programs should offer treatment in a therapeutic milieu where a sense of trust and safety exists, and where efforts to improve and change are fostered and nurtured. Despite the many elements of control that exist within the modality, the way in which programs relate to this control is of vital importance. Thus, if a patient must provide a urine specimen in an atmosphere that suggests punishment and power, trust and patient growth cannot thrive. There is an inevitable tension that exists in programs that appropriately use urine screening in decision making and in conferring take-home privileges. Therefore, it is important to consider the entire process of collecting urine specimens and the ways in which results are used.

Ideally, urine specimens should be obtained randomly, on the basis of the patient's clinic visit schedule. Random lists can be generated by computer or by the clinic manager. Patients should be informed about how urine specimens are collected and of the responsibility to provide a specimen when asked. The bathroom used for collection should be cleaned frequently and always supplied with soap and toilet articles.

While programs employ various strategies to minimize the likelihood of falsification of samples, such strategies should be balanced by the treatment ethic and the overall goal of the program—rehabilitation through long-term treatment. The hot water should be turned off in the bathroom where urine samples are provided to prevent heating specimens brought from elsewhere. The designated bathroom should be within eyesight of the staff monitor to preclude use by more than one person at a time, and the specimen that is collected should be felt for warmth (freshly voided specimens are always body temperature, approximately 37°C.). Some clinics use a thermometer strip; others use a collection device with a thermometer strip included. Many treatment programs collect specimens under direct observation, while others use one-way mirrors and even videotape to ensure reliable sample collection. In most cases, direct observation need not be employed in collecting urine specimens unless chain of custody is a major concern. If direct observation is used, it should be done ethically with respect for patient privacy and should be handled professionally and in a manner that does not damage the patient-clinic relationship. Whichever method is used, specimens should be collected in a manner that minimizes falsification. Appropriate precautions for handling urine specimens (for example, the person collecting the specimen should always wear gloves) should always be taken.

Falsification is best minimized if patients do not feel that the urine results will be used to punish them. Continued use of drugs is a treatment problem that requires counseling, casework, medical review, and other interventions, not punishment. The treatment literature contains reports of programs that reduced methadone doses as the direct result of positive urine reports or discharged patients from treatment as a result of a number of consecutive positive reports. Such responses pit patient against program and do not promote trust or quality patient care. Rather, patients should be encouraged to discuss their substance use with program physicians, caseworkers, or counselors. Ideally, urine screening results should simply confirm what has already been discussed in individual or group sessions. Nevertheless, some patients fear loss of take-home privileges or remain in denial about their drug use, and the urine screen result(s) will alert the program to the

patient's substance use. Positive urine results should always be discussed with the patient, and the patient's response should be recorded in the case record.

Some patients will adamantly deny substance use despite the positive result received from the laboratory. Methadone maintenance treatment providers should take adamant denial seriously and not discount the patient as a manipulator or a liar. A careful history of any prescribed or over-the-counter drugs used by the patient should be obtained. This history should be discussed with the laboratory pathologist or chemist to determine if these drugs can result in a positive screen or confound the result in any way. Wherever possible, the positive screen (if the specimen is still available) should be retested and confirmed by another method. If this is not possible, future screens should be ordered with confirmation. More accurate testing methods such as RIA or GC/MS can also be used to verify the laboratory report. Urine can be collected under direct observation and a chain of custody can be maintained to assure the patient that every effort is being made to prevent laboratory error and to respond to the patient's denial.

Most methadone maintenance programs experience a significant number of urine reports positive for drugs of abuse or negative for methadone that must be reviewed and addressed. Positive urine reports for heroin should signal a medical review of dosage as well as substance abuse and HIV counseling. All positive reports should trigger a clinical response, which should be explained to the patient in treatment terms, even when loss of privileges is warranted. Likewise, because of regulatory concern about methadone diversion, reports that are negative for methadone should also be carefully evaluated. Again, urine results should not be used to punish patients, but rather to allow the clinical team to explore different treatment techniques to address this substance abuse (see ch. 3 and 8).

By coupling the collection of urine specimens with therapeutic regimens, some MMTPs have been able to aid the delivery of health and social services, thus reducing the "control" aspect of urine screening. At the Albert Einstein College of Medicine and the Montefiore Medical Center programs in New York City, urine is obtained monthly from all consenting female patients and tested for pregnancy. (See attachment 1 for a sample patient consent form for pregnancy testing.) This process is easily combined with the collection of urine for drug screening and has allowed those programs to assist female patients to recognize pregnancy as early as possible and to consider early prenatal care and other options to improve the outcome for patient and child. In this way, the program helps to cast the urine collection procedure in as positive a light as possible.

Administrators should also monitor urine reports to ensure compliance with State and Federal regulations and to discover trends in drug use that require a redirection of clinical and fiscal resources. Within the past 15 years, drug use patterns have changed markedly as barbiturates, amphetamines, sedative-hypnotic drugs, and cocaine became popular drugs of abuse. Each drug presented different treatment implications as well as funding concerns. Urine reports proved helpful in monitoring the extent of these emerging patterns. Administrators can also use these reports to monitor program effectiveness. For example, an MMTP that is prescribing adequate dosages of methadone should not have more than 10 percent of program urine reports positive for opiates. Just as importantly, almost 100 percent of the program's urine reports should be positive for methadone, as significantly lower percentages would indicate possible methadone diversion that would require administrative action. Methadone maintenance treatment program administrators should ensure that urine is screened randomly and with required frequency. They should also ensure that positive urine reports (and negative methadone urine reports) are addressed by clinical staff appropriately and that the reports and responses are documented in the case record.

Patients who continue to use illicit drugs or nonprescribed psychoactive medications while maintained on methadone are a major source of concern and regulatory actions by FDA and DEA, which are concerned about possible diversion by patients who abuse drugs. In fact, the highest number of FDA citations is for the failure to use urine-screening results to decrease the number of permitted take-home doses (Molinari, personal communication, 1991). DEA and FDA relate diversion to continued use of illicit drugs by patients and to take-home supplies. The MMTP can help to address these concerns by carefully documenting collection methods that prevent false specimens and clinical responses to urine reports positive for drugs of abuse or negative for methadone.

Issues and Concerns

MMTPs are clinical programs that must balance regulatory concerns about administering the controlled substance, methadone, with good clinical treatment. Urine screening highlights this delicate balance and requires the program to carefully assess its policies and procedures to

provide quality care while preventing methadone from being misused or diverted. In most health care settings, preliminary screening is done but not on a regular and consistent basis. Testing is routinely done to confirm clinical impressions and to assist in diagnosis. In MMTPs, staff need to prevent the use of urine results as the only means of detecting substance abuse problems in patients and need to ensure that the treatment needs of patients whose reports show no substance abuse are not ignored. Too often, overworked counselors and caseworkers scan urine lists to detect reports that are positive for drugs of abuse or negative for methadone as a means of providing service, without investing the time and effort to develop the trust and concern inherent in a successful counseling relationship. Training and education for staff concerning urinalysis can help ameliorate this situation. Frank discussion of the issues involved for patient and program will also help the clinicians understand the benefits of these reports.

One major concern for regulatory agencies and programs is the frequency of urine screening. Given the cost and nagging questions about the reliability of urine screening, some programs limit urine screening and others ignore results as unreliable. These are real issues that confront programs and require thought and balance. However, the frequency of urine screening should be clinically appropriate for each patient and allow for a concerned and rapid response to the possibility of relapse. Urine screens should be performed with sufficient frequency to assist in making informed decisions about take-home privileges. For those patients who continue to abuse drugs or have negative methadone reports, weekly urine screens should be continued. Patients who visit the clinic weekly or less than weekly should provide a urine specimen at each clinic visit. Screening at this frequency provides protection to patients who are vulnerable to relapse because long periods will not elapse before therapeutic intervention can be initiated. However, programs should not make clinical decisions that affect patients' lives based solely on urine reports. Results should be discussed with the patient and weighed along with other relevant issues in treatment. Confirmatory procedures or more sophisticated methodology should be used if the patient denies use despite the positive screening report.

Concerns about methadone maintenance treatment patients who sell their medication and the consequent negative effect diversion has on both the effectiveness of treatment and public acceptance of methadone maintenance treatment have resulted in increased regulatory oversight. Because of concerns about diversion, FDA investigators pay particular attention to urine results and whether the treatment program has initiated appropriate followup regarding the frequency of take-home medications when the urine screen results are negative for methadone or positive for drugs of abuse or both. As a result of this increased scrutiny, many programs have been cited by regulatory agencies with failure to adhere to urine requirements and with providing inadequate treatment. It is also inferred that these violations have resulted in increased diversion. In addition to the FDA actions, DEA has relied on the FDA reports of compliance with urine test results in its "show cause" actions. As a result, many MMTPs have begun to rely solely on urine reports as the criterion for determining take-home privileges.

However difficult it may be to correlate diversion to urine reports, programs should adequately document the basis for providing take-home medication to patients, particularly if a report is negative for methadone or positive for drugs of abuse. Programs should also provide a rationale for the screening methodology used by the urine laboratory. Programs with laboratories using TLC should be aware that low doses of methadone occasionally yield negative reports and, the lower the dose, the more common this occurrence becomes. Although urine reports should be considered as one parameter in deciding take-home privileges, other considerations, such as employment, must be taken into account and documented as part of the decision. (The Federal regulation 21 CFR § 291.505(d)(6)(iv) outlines eight criteria that must be considered when granting take-home privileges.) Often, privileges are removed simply to prevent possible medication diversion without concomitant programmatic response related to the positive urine reports. When this occurs, the program creates a barrier between the patient and the program and seems to function more as a monitoring and surveillance unit than as a treatment program; patients respond accordingly.

Another critical issue is the reliability of the urine screens (Blanke 1986; Morgan 1984). Programs have argued that frequent screening or use of the results in treatment decisions is not warranted because the results are not reliable. While it is important to understand the difference between the various methods laboratories use and the limitations of some of the tests, urine screening is basically reliable, particularly if a program monitors for trends and does not act on a single, isolated screen. It is important to understand that accuracy depends

on choice of laboratory, use of proper equipment and methodology, quality control, and use of high-quality standards by all involved in the screening. In all laboratory testing, human errors, confounding results, chain of custody of the sample, and other problems can occur. Informed decisions by programs can reduce these problems markedly.

The literature on the accuracy of urine toxicology in MMTPs is sparse; however, several studies have been done to measure the accuracy of the screening techniques generally used. In the main, the studies report an accuracy level for screening techniques that is at least 70 percent of that of the RIA or GC/MS, depending on the technique used. On the basis of the vast differences in cost, the techniques used are adequate for methadone maintenance treatment. When results are contested or confusing, confirming tests should be used. For example, when EIA is used and patients deny any drug use, confirmation TLC can be useful. These confirmations help offset the limitations of the screening techniques, though in general practice, confirmations are not necessary.

Summary

Urine screening in MMTPs can provide clinical guidance, as well as administrative information for quality assurance and program planning. However, care should be taken to conduct screening in a therapeutic and humane environment, and the results should be used to confirm clinical impressions, to assist with the care of the patient, and to help modify treatment plans. Regulatory agencies and program staff should be properly trained and educated about the tests used by the program so that their benefits and limitations can be understood. Results should be documented in the clinical record along with an appropriate justification, particularly if take-home medications are continued despite consistent positive urine results.

Recommendations

- View Federal urinalysis requirements as minimal and regulatory; evaluate clinical needs and develop policies and procedures to integrate urinalysis into treatment planning and clinical practice.
- Obtain urine specimens in a treatment atmosphere that suggests a sense of trust and safety, rather than punishment and power.
  - Obtain specimens randomly on the basis of the patient's clinic visit schedule.
  - Inform patients about how urine specimens are collected and of the responsibility to provide a specimen when asked.
  - Ensure that the bathroom used for collection is clean and always supplied with soap and toilet articles.
  - Collect specimens in a manner that minimizes falsification; if using direct observation, carry it out ethically with respect for patient privacy.
- Discuss positive urine results with the patient, and document these results in the clinical case record; also record the patient's response.
- Provide counseling, casework, medical review, and other interventions when continued use of drugs is a treatment problem; punishment is not appropriate.
- Take seriously the patient's adamant denial of drug use, and investigate the possibility of a false positive.
- Review dosage when positive urine reports for heroin and other drugs are obtained, and provide substance abuse and HIV counseling; evaluate carefully reports that are negative for methadone.
- Monitor urine reports to ensure compliance with State and Federal regulations, discover trends in drug use that may require a redirection of clinical and fiscal resources, ensure that positive urine reports are addressed appropriately by staff, and ensure that reports and responses are documented in the case record.
- Ensure that the frequency of urine screenings is clinically appropriate for each patient and allows for a concerned and rapid response to the possibility of relapse.
- Perform urine screens with sufficient frequency so that they can be used to assist in making informed decisions about take-home privileges; however, program staff should not make clinical decisions based solely on these reports.
- Evaluate the quality of the laboratory that is selected to perform urine screens, the laboratory's use of proper equipment, methodology, and quality control; also ensure use of quality standards by all involved in the screening.
- Properly train and educate regulatory and program staff about the tests and procedures used by the MMTP so that their benefits and limitations can be understood.

References

Blanke, R.B. Accuracy in urinalysis. In: *Urine Testing for Drugs of Abuse*. National Institute on Drug Abuse Research Monograph 73. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1986. pp. 43–53.

Coffman, N.B., and Fernandez, J. Drugs of abuse testing. *Journal of*

the American Osteopath Association 91(4):385–388, 395–396, 1991.

Daistha, K.K., and Tadrus, R. Comparison of costs for testing a wide variety of drugs of abuse per urine specimen in a drug abuse urine screening program and frequent urine collections. *Journal of Chromatography* 109(1):149–162, 1975.

Hawks, R.D. Analysis methodology. In: *Urine Testing for Drugs of Abuse.* National Institute on Drug Abuse Research Monograph 73. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1986. p. 60.

Manno, J.E. Interpretation of urinalysis results. In: *Urine Testing for Drugs of Abuse.* National Institute of Drug Abuse Research Monograph 73. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1986. pp. 31–32.

Morgan, J.P. Problems of mass urine screening for misused drugs. *Journal of Psychoactive Drugs* 16(4):305–317, 1984.

New York State Division of Substance Abuse Services. *1990 Substance Abuse Services and the Law.* Albany, New York, 1990.

Saxon, A.J.; Calsyn, D.A.; Haver, V.M.; and Erickson, L. A nationwide survey of urinalysis practices of methadone maintenance clinics: Utilization of laboratory services. *Archives of Pathology and Laboratory Medicine* 114(1):94–100, 1990.

Schwartz, J.G.; Zollars, P.R.; Okorodudu, A.O.; Carnahan, J.J.; Wallace, J.E.; and Briggs, J.E. Accuracy of common drug screen tests. *American Journal of Emergency Medicine* 9(2):166–170, 1991.

For Further Reading

National Institute on Drug Abuse. *Urine Testing for Drugs of Abuse.* National Institute on Drug Abuse Research Monograph 73. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1986.

Attachment 1

ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY

DIVISION OF SUBSTANCE ABUSE

EARLY DETECTION OF PREGNANCY: PATIENT CONSENT REGARDING ROUTINE PREGNANCY TESTING

I,_____, have been informed that the Albert Einstein College of Medicine, Division of Substance Abuse, seeks to detect pregnancy as early as possible in patients enrolled in its programs. This effort is being made to minimize problems associated with pregnancy and so that necessary medical and social services can be provided to help ensure the health of both the mother and the unborn child.

I understand that early detection of pregnancy will enable me to take advantage of preventive care that is practical and useful. Therefore, I agree that the Division of Substance Abuse may perform a pregnancy test from a urinalysis specimen submitted by me for that purpose on a monthly basis. I understand that I will be informed of the test results as soon as possible after they are received by the Division.

I am aware that the Division provides comprehensive services for pregnant patients, including prenatal medical care and family assistance and that those services will be available to me should I become pregnant. I will make every effort to follow the Division's instructions and guidance regarding pregnancy and make every effort to participate in the services offered to me. I will do my best to advise the clinic staff if I suspect that I may be pregnant.

I understand that this consent is offered so that the Division can provide the best possible medical and social services for me and my unborn child should I become pregnant. I understand that if I refuse to sign this consent, no adverse consequences will occur and that I will continue to receive substance abuse treatment at the Division without interruption or prejudice. I understand that this consent is freely given and that I may revoke it at any time.

_____	_____	_____
Date	Patient Signature	Witness

Chapter 7—Responsible Take-Home Medication Practices

Lawrence Brown, Jr., M.D., M.P.H.

The responsible use of methadone—like treatment practices regarding use of any pharmacological agent—requires adequate attention to certain key clinical and social issues. Such issues include the fundamental scientific principles of the drug's pharmacokinetics and pharmacodynamics, the abuse potential of the drug, the level of community support (or lack of support), and the characteristics of the targeted patient population. This chapter focuses on one important aspect of methadone maintenance treatment for narcotics addiction: take-home medication practices.

Take-home medication refers to those doses of methadone consumed by the patient under conditions of no direct observation by a medical provider. Section 291.505(d)(6) of the Federal regulations governs the administration of take-home medication (21 CFR, Part 291). Additionally, in many States, the SMA provides general to specific amplification of the Federal regulations pertaining to requirements for patients who may receive take-home methadone.

Providers who want to initiate take-home methadone practices should first consult their State agency for regulatory guidance. The general principles covered in this chapter are not meant to substitute for current State regulations. This discussion emphasizes key areas for programs to consider, covering the clinical indications for take-home medication and guidelines for monitoring patients who receive take-home medication.

Factors To Consider With Take-Home Methadone Treatment

Federal regulations (21 CFR, § 291.505(d)(6)(iv)(B)(1)) require that the methadone maintenance treatment program physician

> consider the following in determining whether, in his or her reasonable clinical judgment, a patient is responsible in handling narcotic drugs:
>
> (1) Absence of recent abuse of drugs (narcotic or nonnarcotic), including alcohol;
> (2) Regularity of clinic attendance;
> (3) Absence of serious behavioral problems at the clinic;
> (4) Absence of known recent criminal activity, e.g., drug dealing;
> (5) Stability of the patient's home environment and social relationships;
> (6) Length of time in maintenance treatment;
> (7) Assurance that take-home medication can be safely stored within the patient's home;[1] and
> (8) Whether the rehabilitative benefit to the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

For patients enrolled in methadone maintenance treatment, regular attendance is important and is a corollary to good clinical outcome. There are times during treatment, however, when patients may demonstrate a need for a more flexible schedule than daily clinic attendance provides. Less frequent attendance may also be significant in enhancing the rehabilitative process or in improving the patient's response to other concurrent clinical conditions. It is crucial to avoid providing take-home medication to patients who cannot sufficiently safeguard the methadone from abuse or diversion.

A number of factors are important in attempting to strike an appropriate balance between the beneficial effects and the negative consequences of take-home medication. Specifically, the following positive factors should be considered when deciding to initiate or continue a patient's take-home methadone:

- The patient has remained in treatment for a sufficient period.
- The patient shows no signs or symptoms of withdrawal.
- Biochemical assessments in past 90 days reflect the following results:
  - Urine toxicologies show an absence of illicit drugs and the presence of methadone.

  - Serum methadone levels are determined to have remained in the therapeutically optimal range.
- The patient has no current untreated alcohol abuse or dependency.
- Take-home medication will aid in the care of a patient's concurrent medical disorder(s).
- The patient is in compliance with care for a concurrent alcohol, medical, or psychological disorder.
- Take-home doses will enhance a patient's rehabilitative potential by allowing the patient to participate in employment, education, vocational training, or parenting of infants or small children.
- Take-home doses will be appropriate in a patient's emergency circumstances, such as personal or family crises, bereavement, or other hardships.

Factors that may affect a decision *not* to provide take-home medication may include the following:

- The patient shows signs or symptoms of drug withdrawal or continues to demonstrate illicit drug use.
- The patient suffers from a concurrent disorder that may be complicated by administering methadone and thus requires more frequent clinical observation and supervision.
- The patient is not in compliance with the treatment for an acute or chronic concurrent medical or psychological disorder.
- The patient displays behavioral patterns (e.g., ongoing criminal activity) that may indicate he or she may not be a good candidate for take-home medication.
- The patient's unstable home environment or family relationships pose a risk of diversion or accidental use of the take-home medication.

There is absolutely no scientific validity in using the level of the daily methadone dose as a criterion in determining whether a patient should receive take-home methadone or how many take-home doses he or she should receive. Whether the patient is receiving 60 mg or 100 mg daily is not an appropriate consideration in determining the utility of take-home medication for a given patient. The only exception to this principle is the Federal regulation requiring that patients on 100 mg of methadone have special authorization to receive take-home medication (CFR, § 291.505(d)(b)(vi)). If a patient is on an appropriate dose of methadone, then the risk of abuse or diversion is reduced.

In clinical practice, two or more of the factors discussed in this section may apply in evaluating the appropriateness of take-home methadone for a patient. These clinical evaluations require the input of many disciplines to assess the various medical, social, and rehabilitative factors relevant in determining the appropriateness of take-home medication. A team of representatives from the appropriate disciplines offers the best opportunity for accumulating and discussing the necessary information regarding take-home medication for each patient. While Federal regulations emphasize the role of the physician or his or her designee, a multidisciplinary team approach holds the best prospects for providing the needed comprehensive review.

Factors Supporting Initiation of Take-Home Methadone Treatment

Sufficient Length of Time in Treatment

Duration of treatment is one important factor in determining whether take-home medication will be appropriate for a given patient. In fact, Federal regulations correlate the number of allowable take-home medication doses with the length of enrollment. Evidence supports the premise that the longer the period of enrollment, the greater the prospect of recovery (Ball et al. 1988). It therefore intuitively makes sense that the longer a patient is enrolled in treatment, the more appropriate the patient is for take-home medication. Obviously, this supposition assumes that all other pertinent clinical issues have been addressed, such as whether the patient is working, going to school, parenting small children, or participating in other constructive activities.

We do not know at what point take-home medication should be initiated. We have virtually no scientifically validated evidence that substantiates whether a methadone treatment provider should begin offering take-home doses at 2 months, 3 months, or 1 year. Consequently, many clinicians consider additional factors—as well as guidance from the regulations—in determining when to start a patient on take-home medication.

Attainment of Clinical Stability

Another factor that requires attention is whether physical or psychological signs of drug withdrawal are present. The continued presence of symptomatology implies that the patient has not reached clinical stability. A patient who still shows signs or symptoms of drug withdrawal should not be considered for take-home doses; such a patient should instead receive more frequent—not fewer—clinical observations.

Demands of a Concurrent Medical Disorder

The existence of a concurrent medical disorder and its degree of severity represent additional important considerations in determining if take-home medication is clinically appropriate.

For patients with concurrent diseases that result in impaired ambulation, reduced clinic attendance may be required to aid recovery and to prevent complications in the concurrent disease. In these cases, take-home medication becomes a medical necessity in the classical sense.

This situation is particularly pertinent today because a disproportionately high number of persons with HIV infection and disease are IDUs (CDC 1992). At advanced stages of HIV-spectrum disease, complications moderately to severely limit a patient's ability to ambulate. This incapacitation may be caused by an impaired musculoskeletal system, as well as by severely compromised cardiopulmonary functions. In such circumstances, take-home methadone would ensure that the patient's HIV-spectrum disease does not interrupt the daily methadone dose. Still, some caregivers express the concern that, in some patients with substance abuse histories, the clinical response to advanced HIV-spectrum disease may be increased illicit drug use. If a patient can mount efforts to continue drug-seeking behaviors, then the rationale for reduced clinic attendance is weakened.

Enhancement of Rehabilitative Potential

Another important issue in recommending take-home medication involves reviewing whether this approach may help rehabilitate a given patient. Patients make rehabilitative progress through activities that effectively aid them in becoming valuable contributors to their families and communities through employment, education, and other important endeavors. Consequently, it is important that clinicians encourage patients to participate in these activities. To the extent that take-home methadone will enable patients to engage in these activities, take-home medication is crucial in the recovery of these patients.

Emergency Circumstances

Finally, there are a few emergency circumstances in which a limited number of take-home doses may be appropriate. These include personal or family crises, travel, bereavement, or some other hardship.

The issue of travel raises a few concerns. On the one hand, it is reasonable to assume that patients (and their families) at advanced stages of rehabilitation would benefit from quality periods of enjoyment, such as a vacation. On the other hand, clinicians should select patients who are appropriate candidates for take-home doses during vacation periods. If there is an appreciable concern about abuse or diversion of the take-home medication, clinicians should consider the benefit of having patients receive their methadone at clinics close to their travel destinations.

Factors Arguing Against Take-Home Methadone Treatment

Signs or Symptoms of Drug Withdrawal

Patients should not be considered for take-home dosages until they have reached clinical stability. There are laboratory measures that can assist in cases in which there are no clinical cues. Take-home medication would be inadvisable for patients who continue to demonstrate illicit drug use as evidenced by urine toxicological tests, whose toxicological tests do not reflect methadone administration, or whose blood serum levels of methadone are suboptimal. The following reasons are evident:

- Continued illicit drug use places the take-home doses at risk for possible diversion.
- Biochemical evidence of an absence or suboptimal level of methadone may indicate inadequate attendance patterns, methadone diversion, or another medical concern deserving attention.

The sensitivity and specificity of the various methods for assessing illicit drug use have important clinical implications, especially in identifying those patients who continue to use illicit drugs. However, we must recognize two important caveats in using various laboratory methods. First, while the risk of false positives in a high-risk population (for substance abuse) is generally small, the risk of false negatives varies with the laboratory methods used. Second, very few laboratories have the capability to measure serum methadone. As knowledge and capabilities to serologically measure methadone increase, pressures also increase on clinicians to use more objective, specific, and sensitive instruments of clinical status (Henderson and Harkey 1990; Inturrisi and Verebey 1972).

Potential Complications Resulting From Concurrent Disorders

Even in cases of non-HIV-related diseases, such as multidrug-resistant TB, administering methadone may potentially complicate a concurrent disorder or the care of such a disease. When this potential exists, take-home medication is ill-advised until the risks of an undesirable clinical outcome have diminished.

This consideration is important also because agents used to treat concurrent medical disorders may affect the bioavailability of methadone and potentially induce withdrawal symptoms; for example, rifampin used to treat TB

can interact with methadone and produce withdrawal symptoms, requiring an increase in methadone dosage (Kreek et al. 1976). In these instances, more frequent clinical observations are important to monitor the concurrent disease, to avoid methadone-related complications of the concurrent disorder, and to ensure that the pharmacological benefits of administering methadone are maintained during the course and treatment of the concurrent disease.

Other Adverse Indicators

Patients who do not comply with the care of an acute or chronic concurrent disease are poor risks for take-home medication. Other poor candidates include patients who are abusing other drugs or alcohol or responding poorly to efforts to treat diseases. Under the disinhibiting effects of these other substances, these patients may not be able to safeguard or adequately store their take-home doses.

Nonmedical Indications Against Take-Home Medication

Some nonmedical factors, such as behavioral issues, also serve as arguments against providing take-home medication. Antisocial behavior, for example, may be associated with the inappropriate or unauthorized use of take-home methadone. Patients who do not conduct themselves appropriately within the clinic or who are known to engage in ongoing criminal behaviors do not represent good candidates for take-home medication.

The appropriateness and stability of the home environment are also key to the safety and storage of methadone. In homes where social relationships are unstable, there is a significant risk that methadone medication may not be adequately secured from diversion or accidental use (as with children).

Monitoring Patients on Take-Home Medication

Monitoring patients who receive take-home methadone requires the same careful clinical review as does instituting take-home medication. The status of every patient provided take-home medication should be reviewed by a physician at least every 90 days (or more frequently as clinically indicated) for as long as the patient is granted this privilege.

Review of the merits and drawbacks of continuing take-home medication should be comprehensive, since staff from various disciplines can provide valuable input. A multidisciplinary team approach is a suitable method for sharing pertinent information about whether to continue or discontinue take-home methadone. Accordingly, a multidisciplinary team meeting would be the appropriate forum for such decisions. While Federal regulations place the burden of assurance upon the prescribing physician, the multiteam approach has another distinct advantage: The patient cannot manipulate one discipline against another when there is consensus in the ultimate clinical decision.

Issues for Review

The rationale for initially providing take-home methadone to a patient should be reviewed and documented to determine whether those justifications continue to apply. For example, if employment as a way of advancing the patient's rehabilitative process was one of the original reasons for permitting take-home medication, then the patient's continued employment should be verified. If a concurrent medical disorder was the basis for the take-home methadone, then a medical reassessment is necessary to determine whether the clinical status of the concurrent medical disease still warrants reduced clinic attendance.

Reviewing the original rationale for take-home medication is necessary but not sufficient. The monitoring process should also include an assessment of whether or not reasons exist to rescind the take-home medication. Medical, psychological, behavioral, or social reasons to rescind may have come to the attention of the clinicians subsequent to providing take-home medication. As an example, take-home methadone should be discontinued if the patient provides any clinical symptomatology of withdrawal or if the patient is no longer in compliance with the care of a concurrent medical disease. Similarly, when a patient complains of stress at work or at home, the patient's ability to handle the stress should be assessed. Continued take-home privileges may not be advisable if the degree of stress is significant or if the patient is unable to handle the stressor(s).

Biochemical Monitoring

Additionally, biochemical monitoring should continue to ensure that the patient is free of illicit drug use and is consuming the methadone provided. This goal can be met through random urine screens. If serum methadone levels are available, the clinician will have the added advantage of determining whether the serum methadone levels remain in the therapeutically optimal range. Obviously, biochemical assessments are subject to the same caveats described earlier.

In the monitoring process, methadone clinicians can implement the following measures to help avoid diversion of the methadone:

- Provide doses dissolved in a liquid or use methadone in liquid form (see DEA

regulations, app. B). If the Disket is used, it should be dissolved in a liquid.
- Label each bottle of take-home medication with the patient's name, the dose, the source clinic, the prescribing physician, and the date the dose is to be consumed (see FDA regulations, app. B).
- Require patients to return all empty take-home dose bottles on their next day of clinic attendance following the take-home dosing. Clinic staff who accept the bottles should inspect them to ensure that the bottles are coming from the appropriate patient during the appropriate period.
- Institute clear clinic procedures for responding to patients who frequently fail to return, or who have unverified reasons for failing to return, empty take-home bottles. Take-home medication should be discontinued for such patients. While there may be perfectly valid reasons for the rare failure to return a bottle, clinicians should review the frequency and circumstances of this noncompliance with clinic policy. Such careful review is critical if the clinician is to meet the responsibility for ensuring that patients adequately safeguard their take-home doses.

Summary

Take-home medication is an important clinical tool in methadone maintenance treatment. Federal regulations stipulate the minimum boundaries governing use of take-home methadone; these minimum standards have been refined by the regulations of many State substance abuse or public health agencies. There is still sufficient latitude for treatment providers to make clinically relevant decisions about the merits and drawbacks of take-home medication for a given patient. The decision to initiate or continue take-home methadone should include a review of medical, psychological, behavioral, and social issues. While Federal regulations focus on the prescribing physician, the success of the take-home methadone decision requires multidisciplinary input.

When take-home methadone is implemented responsibly, the decision reflects an informed judgment on three converging issues: The scientific validity of using methadone, the potential of the clinical setting, and the special characteristics of the patient population. Furthermore, carefully rendered take-home medication may extend positive effects beyond the opioid-dependent patient to the patient's family and community.

Recommendations

- Use a team of representatives from the appropriate disciplines (e.g., physicians, nurses, and counselors) to accumulate and discuss the necessary information regarding take-home medication for each patient.
- Do not use the level of the daily dose to determine whether a patient should receive take-home medication.
- Consider the following factors in supporting initiation of take-home medication: Sufficient length of time in treatment, attainment of clinical stability, progress in rehabilitation, medical necessity, behavioral factors, and emergency circumstances.
- Consider the following factors as arguments against take-home medication: Signs or symptoms of withdrawal, continued illicit drug use, the absence of laboratory evidence of methadone in urine samples, potential complications from concurrent disorders, ongoing criminal behavior, and an unstable home environment.
- Have the status of every patient provided with take-home medication reviewed by a physician at least every 90 days (or more frequently if clinically indicated) for as long as the patient is granted this privilege, and have staff from various disciplines review the merits and drawbacks of continuing take-home privileges.
- Use biochemical monitoring to ensure that the patient is free of illicit drug use and is consuming the methadone provided; implement other measures to help avoid diversion.
- Provide guidance to patients for securing methadone take-homes in their places of residence.

References

Ball, J.C.; Lange, W.R.; Myers, C.P.; and Friedman, S.R. Treatment effectiveness in reducing intravenous drug use. *Journal of Health and Social Behavior* 29:214–226, 1988.

Centers for Disease Control, HIV/AIDS Surveillance, January 1992.

Henderson, G.L., and Harkey, M.R. *The Use of Therapeutic Drug Monitoring To Improve the Effectiveness of Methadone Treatment Programs.* Department of Alcohol and Drug Programs, State of California, January 1990.

Inturrisi, C.E., and Verebey, K. The levels of methadone in the plasma in methadone maintenance. *Clinical Pharmacology and Therapeutics* 13:633–637, 1972.

Kreek, M.J.; Gutjahr, C.L.; Garfield, J.W.; Bowen, D.V.; and Field, F.H. Drug interactions with methadone. *Journal of the New York Academy of Sciences* 281:350–371, 1976.

Endnote

1. As required by Federal regulations (P.L. 91-601, 15 U.S.C. 1471), take-home doses must be provided in child-proof, tamper-proof containers.

Chapter 8—Treating Multiple Substance Abuse

Andrea Barthwell, M.D.
David R. Gastfriend, M.D.

The high frequency of concurrent opioid dependence and other substance abuse poses a problem for methadone maintenance treatment, and unfortunately, research in this area is scant. The most serious multidrug problem in methadone maintenance treatment is increased mortality associated with unmonitored drug combination use. The leading causes of death in methadone-maintained patients are use of alcohol and opioids other than methadone, both during and after treatment. Furthermore, alcohol use is responsible for significantly decreasing the 10-year survival rate of methadone-maintained patients.

Common clinical experience has shown us that people in methadone maintenance programs who use drugs in combination with methadone fall into one of two groups. There are those who use drugs to get high as a continuation of street life (most often using cocaine, alcohol, benzodiazepines, marijuana, and sometimes tricyclic antidepressants) and those who use drugs in addition to methadone for quasi-legitimate or clinically evident reasons (back pain, insomnia, headache, or some other concurrent DSM III-R illness).

Addict populations probably have an overrepresentation of people with chronic musculoskeletal problems, back pain, depression, insomnia, and anxiety disorders; these conditions do in fact often require drug treatment. The challenge for each clinician is to make appropriate assessments to determine if nonprescribed use is therapeutic (for clinically evident or quasi-legitimate conditions) or nontherapeutic. For nonprescribed therapeutic use, the clinician should assess the efficacy and safety of the drug(s) in question and substitute the most appropriate pharmacological agent that safely addresses the condition being treated. Ongoing monitoring of the use of the prescribed agent is then required to assess whether the patient is complying with the therapeutic regimen. The clinician should be cautioned that merely substituting an appropriate agent does not ensure that the patient will take it as prescribed and immediately discontinue use of illicit substances that, from the patient's perspective, may also have desirable side effects (e.g., euphoria, sedation, etc.).

For nonprescribed nontherapeutic use, the challenge for each clinician is to continue to search for treatment interventions that may be altered to enable the patient to take the next step along the continuum of recovery. Within methadone maintenance programs, people who continue to use drugs need to be monitored closely and worked with consistently in a number of areas of potential impact; a good treatment program is one that uses many techniques to decrease the morbidity and mortality associated with substance use. We emphasize using a variety of techniques and considering all that is available to us. This is because, despite what we would like to believe, treatment technology is not developed to the point that we know what to do with a sizeable faction of people in our clinic population who use a variety of substances for a variety of purposes (e.g., nicotine, alcohol, benzodiazepines, marijuana, etc.).

A strong historical correlation between opioid abuse and alcohol abuse exists. Despite this, most States have administered alcohol and drug services separately, to the likely detriment of methadone maintenance patients. Further, the comorbidity of opioid dependence and psychiatric diagnoses with other substance abuse has been little studied. As a result, treatment recommendations can be extrapolated only from data about single substance dependence.

Prevalence of Other Substance Use During Treatment

As stated above, methadone maintenance patients frequently use other substances. The use of an opioid in combination with another substance generally does not start in the methadone maintenance program setting, as evidenced by the facts that alcohol in

combination with heroin and cocaine and cocaine in combination with heroin are the second and third most common drug overdose patterns resulting in emergency room visits, respectively (Drug Abuse Warning Network 1990). The popularity and efficacy of "doors and fours," i.e., codeine containing cough syrup with glutethimide (Doriden) reflects the fact that opioids and sedative-hypnotics are effective pharmacological admixtures.

Stimulant use is extremely high among heroin users and can be expected to persist as methadone maintenance treatment is initiated, since methadone does not treat stimulant dependence. In one sample, 74 percent of heroin addicts seeking treatment had recently used cocaine (Kosten et al. 1987), and other programs have reported as many as 33 percent of patients in methadone maintenance treatment with cocaine-positive urines in a given month (Kolar et al. 1990).

Marijuana and benzodiazepine use also appear to be significant problems during methadone maintenance treatment. In a study of 300 urine samples drawn from two methadone maintenance programs in two east coast cities, 27 percent and 51 percent of samples were found to contain evidence of marijuana use (THC) and 4 percent and 7 percent contained benzodiazepine metabolites (DuPont and Saylor 1989). This report raises another important concern: All but one of the positive THC urine samples also contained another drug of abuse, and every sample that tested positive for benzodiazepines also contained another drug of abuse. Thus, a substantial number of patients are at risk for adverse interactions and toxicity from methadone combined with one or more psychoactive drugs.

Another survey of the last 100 admissions to the Chicago methadone maintenance treatment system through Chicago's Central Intake revealed that only 18 percent presented with just heroin or illicit methadone in their initial urine screen (Watkins, personal communication, 1991). Out of 100 admissions, 70 had cocaine metabolites in the urine, 22 had a sedative-hypnotic-anxiolytic, 18 had barbiturates, 4 had benzodiazepines, and 4 were using marijuana in combination with heroin. A total of 14 of the 100 admissions had drugs from more than two drug classes in their urine. (Alcohol is not detected in the urine screen.) In this sample, which is consistent with several published reports, heroin addicts are often not "purists" in their use of drugs.

Phenomenology of Other Substance Abuse in Methadone Maintenance

Methadone prevents withdrawal from opioids, prevents drug hunger for opioids, and, when given in adequate amounts, blocks the euphoria-producing effects of other opioids. These pharmacologic actions yield the primary goal of methadone—cessation of illicit opioid use. In contrast, secondary goals include cessation or reduction of other substance use, antisocial behavior, and disease transmission, and increased productivity or socialization. Despite the fact that all of these secondary goals are demonstrated to occur within methadone maintenance treatment, they are not a direct pharmacological or physiological result of taking methadone. Additionally, comorbid other substance abuse or dependence will impede even the most effective methadone-only treatment strategy and may result in poor performance in other areas. It has been well documented that alcohol use is a major reason for treatment dropout (Joseph and Appel 1985).

Assessment Should Distinguish Between Other Substance Use, Abuse, and Dependence

Many individuals in methadone maintenance treatment also use other substances. This use varies widely, however, and often cannot be generalized. Several categories of concurrent use exist, and effective strategies must accommodate at least a few basic subcategories. These can be considered according to the following scheme.

Other Substance Use

Some individuals will use one or more than one other substance only intermittently, without intoxication, behavioral disturbance, withdrawal, or loss of control. People who present nonprescribed therapeutic use patterns often use in this way. This pattern can be characterized as asymptomatic substance use, and indeed, it does occur, although not nearly as often as claimed. During most of the period of methadone maintenance, eliminating other substance use constitutes an ideal treatment goal. There are patients who may insist that an occasional wine or beer with dinner presents no problem and was never associated with heroin use. Under these circumstances, the abstinence ideal often seems illogical to the patient and is resisted passively and vigorously. Excessive treatment efforts for patients in this category may yield diminishing returns.

Nicotine dependence, despite constituting true physical dependence, seems to many to fall into this category, in that efforts to treat nicotine dependence are often seen by treatment staff as pointless and seem to create unnecessary hostility and control issues with patients. These authors believe,

however, that nicotine dependence presents a significant risk of morbidity and mortality to the patient involved in the MMTP. In that effective technology is being developed for the treatment of nicotine dependence, it must be addressed with the patient within the context of his or her drug use recovery plan. Just as it is no longer acceptable to talk in terms of "hard" and "soft" drugs, it is no longer an acceptable standard of care to ignore the patient's dependence on nicotine.

Other Substance Abuse or Psychological Dependence

Other substance abuse despite terminated heroin use is a more important concern that is distinguished by continued other substance use in hazardous situations or despite knowledge of possible health or life impairments. Psychologic dependence on another substance can be determined if the patient foregoes developing normal academic, social, or work functions, or loses control of other substance use. Ongoing substance use by a opioid addict, whether with heroin or any other substance, is correlated with ongoing involvement in a substance-using lifestyle. This involvement thwarts the addict's ability to engage in normal social roles and gain distance from illicit activities. Even if a patient has ceased opioid use, other substance abuse constitutes a threat to the treatment process and requires ongoing attention.

Other Substance Physiologic Dependence

Physiologic withdrawal from other substances compels their continued use and usually is more dangerous than opioid withdrawal. For example, central nervous system (CNS) depressants, such as alcohol or benzodiazepines, may produce seizures, and cocaine withdrawal may produce suicidal depression.

Assessment Should Determine Patterns of Other Substance Use and Self-Reported Etiologies

The choice of other substances may often be understood by two general principles: clustering and progression. When individuals without a clear preference for a single drug class begin to engage in substance use, they will use whatever is currently available. If marijuana distribution is rampant in a region, a substantial group of users will emerge in a cluster. A cluster of crystal methamphetamine ("ice") users will emerge if cocaine access is reduced by, for example, interdiction and ice comes into increased production.

Progression differs from clustering in that progression represents the continuum of the disease process in terms of severity, route of administration, and drug choice. For example, teens may begin using socially sanctioned substances (e.g., nicotine, alcohol), progress to drugs used through noninvasive routes of administration (e.g., marijuana, benzodiazepines), and, as they gain experience, move on to more invasive routes of administration (injecting) of drugs viewed to be more risky (e.g., heroin, crack cocaine). Individuals who begin using cocaine at parties by snorting may progress to the more highly reinforcing smoked route of administration. Carefully assessing clustering and progression is essential to understanding the patient's environmental and internal challenges to recovery.

Whether one progresses from casual to symptomatic use is highly individualized and depends on several parameters, including amount, frequency and duration of use, initial age of exposure, and coexisting psychopathology. Research has shown that the drugs themselves differ in their ability to induce dependence on the basis of their unique effects on brain cell receptors, routes of administration, rates of onset of effect, and rates of elimination from the body.

Substance Use and Antisocial Personality Disorder

Some multidrug use can be understood as an associated, or secondary, feature of antisocial personality (ASP). Individuals with this disorder exhibit disordered conduct early in life that precedes drug problems, and they progress to multiple substance abuse and dependence as a consequence of their aggressive, impulsive, antisocial behavior. There is a preponderance of data from over 20 years of study showing that ASP appears more frequently among populations of addicted persons than in the general population; however, recent studies have shown that patients with ASP may not be in the majority when all chemically dependent patients are pooled (Rounsaville et al. 1991; Vaillant 1983). These studies are cited to emphasize that ASP is not a prerequisite for chemical dependency and that populations of addicts vary from clinic to clinic.

When asked, patients often report a self-awareness of their initial experiences associated with their substance use. Some can explain their attraction to substances on the basis of enhancement-avoidance reactions. Substances are used to enhance experience (e.g., using alcohol as a "social lubricant" to "loosen up to party"; using cocaine as an "enhancer" to heighten sexual encounters, etc.). Some people use drugs to avoid experiences (e.g., an incest survivor's use of chemicals before sex to facilitate the "numbing out" of the experience, an adolescent using alcohol and marijuana before sex to use the

excuse that "the drugs made me act that way," etc.).

Symptomatic use may derive from the chemical's ability to regulate affect. Individuals may be vulnerable to heroin dependence because of heroin's ability to relieve internal distress and produce euphoria. Separately, one may experience a "magical connection" to cocaine due to its ability to relieve an underlying depression. Some patients may develop unique drug regimens varying throughout the day, using hypnotics at night, stimulants in the morning, and anxiolytics through the afternoon. The reader is cautioned that many individuals in treatment will attempt to attach a rational explanation to their substance use. These explanations are often simple and are presented as excuses for continuing an irrational behavior in the face of overwhelming evidence that the substance use is dysfunctional.

Substitution

A common etiology for other substance use in heroin addicts who shift to another drug of choice after methadone stabilization is the ongoing desire to effect a mood shift. Methadone's long half-life produces no mood swing in most individuals, and tolerance to most of its side effects develops in a matter of weeks. As part of the success of methadone, most patients receiving adequate doses soon discover that they are no longer able to modulate their moods with heroin. Thus, one of the principle reasons for heroin use has been defeated. Often, after making this discovery, the heroin addict seeks another substance to substitute for this function. For this reason, we estimate that as many as half of those entering treatment without a significant history of other substance use will initiate or accelerate such use during the first year of treatment.

Spontaneous Remission

Our clinical experience with individuals who enter treatment is that sometime before the end of the second year of treatment, if retention strategies are employed and the program avoids pressuring patients to eliminate methadone, about one-half of those who initially had a secondary drug problem will experience a "spontaneous" remission. This remission is spontaneous in that the methadone is not primarily directed at physiologic stabilization of the individual for the secondary drug of choice.

Remission from all substance use is a welcome outcome of methadone maintenance treatment. In order to shift the odds toward cessation of all substance use, methadone maintenance programs need to provide a variety of services that support this goal. A clear policy must establish that cessation of all substance use is desired. The policy needs to surmount any ambiguity about abstinence within the context of methadone maintenance treatment being a necessary goal. However, abstinence is not directed at the prescribed therapeutic use of other drugs necessary to treat legitimate, documented conditions.

Because chemical dependency is a chronic disease, there are two basic principles of treatment. The first principle is that a chronic disease requires long-term care and that treatment is a process that occurs over a long period. The second principle is that few chronic diseases respond to a single model of care, and, therefore, a variety of techniques may be appropriate for a patient. Abstinence from other substance use should be long-term or at least for increasing periods, and the patient should experience improved life functioning and well-being.

Pharmacologic Effects of Multidrug Use

Cross-Tolerance vs. Potentiation

In a patient maintained on methadone, the effects of other psychoactive drugs will vary depending on whether they are cross-tolerant with methadone or potentiate it. If addicts who use other opioids while being maintained on an adequate methadone dose experience little or no euphoria, for example, these opioids are cross-tolerant. (An exception is pentazocine (Talwin) because of its different receptor profile. Experienced addicts are aware that pentazocine antagonizes methadone and provokes acute opioid withdrawal. Butorphanal tartrate (Stadol) and nalbuphine HCl (Nubain) are other mixed agonist/antagonist drugs that can provoke withdrawal.)

Potentiation occurs when a second drug has similar effects to methadone, such as sedation, and competes for the same protein binding sites or enzyme systems or both. The result is that some drugs, such as antihistamines or barbiturates, can enhance methadone's opioid effects, a technique known on the street as "boosting." The most substantial effect of the combination, however, given the long-acting pharmacology of methadone, probably is to achieve a stronger-than-usual primary effect from the second drug, for example, antihistamine or barbiturate sedation. Potentiation's greatest risk is the increased likelihood of unexpected lethal overdose.

Prescribed Drugs in the Methadone-Maintained Patient

Rifampin, barbiturates, and tricyclic antidepressants may induce liver

enzymes, which speed the biotransformation of methadone. Patients taking these medications may need increases in the methadone dose to maintain stability. Methadone can be used concurrently with therapeutic doses of antidepressants, antipsychotics, anticonvulsants, anxiolytics, sedative-hypnotics, lithium, and disulfiram if closely monitored (Ling et al. 1983). Methadone and clonidine should not be used concurrently because of the danger of synergism of sedative effects.

Guidelines for Treatment

Basic assumptions underlie any rational approach to treating the multiple substance abuser in an MMTP. First, comprehensive substance abuse care with adequate doses of methadone that are tailored to the patient's physiology, drug use history, and treatment needs is essential. The clinician should consider the possibility that methadone is not producing optimal results because the dose is not producing the sustained blood plasma levels needed for effective maintenance.[1]

Second, treatment retention should be the goal because what we know from many outcome studies over many years is that some treatment is better than none, and longer treatment duration is highly correlated with increased success (Hubbard et al. 1989).

Third, there are few, if any, compelling reasons to abruptly discharge patients from treatment in this era of HIV-spectrum disease. When outpatient methadone maintenance and counseling fail to ameliorate other drug dependence, particularly dependence on cocaine, alcohol, and benzodiazepines, many clinicians feel pressed to consider administrative withdrawal and dismissal. This should not be considered an option. Punitive strategies held over from years past, such as mandatory discharge for positive urines, are no longer practiced. In the past, when patients were discharged, it was believed that at some point their use would drive them back into treatment and that the worst that could happen was a return to illicit heroin use. Today, the threat of HIV and the high mortality rates of people with AIDS should preclude any abrupt discharge from treatment. Additionally, patients prematurely discharged now also face the risks of multidrug-resistant TB and pose a public health threat. Therefore, premature withdrawal and dose limitation can have severe effects on the multidrug-using individual and society at large.

Fourth, answers to the question of why there is concurrent substance abuse should be sought. If reasons are found, the underlying disorder should be aggressively treated. If, for example, a psychiatric disorder exists, the treatment of the disorder needs to occur within the context of drug treatment. This includes educating the patient on the two or more problems, and it may require reeducating MMTP center staff and establishing unique self-help meetings on-site.

Finally, pharmacological agents to treat other dependencies need to be used when there is proven clinical efficacy.

Successful multidrug abuse treatment has undergone only limited research, but several strategies are recommended for both study and implementation. The group at Yale University School of Medicine has recommended early intervention, particularly with people who use cocaine infrequently and in small amounts. Early in the course of a second developing substance dependence, patients may be more amenable to education and have less need of treatments requiring scarce resources such as hospitalization. One obstacle to early intervention is that urine screens, when obtained infrequently, serve to identify only those who use other drugs *on a daily basis* (Kosten et al. 1987). This problem suggests that occasional periods of more intensive urine screening, on a random basis, may be useful.

Careful assessment of psychiatric comorbidity is another early intervention that may be effective. Unfortunately, confusion abounds about what constitutes a psychiatric disorder because of variability in patient reliability and overlapping cycles of drug intoxication and withdrawal. As a solution, several research groups have developed interview techniques that, with proper training, provide logical, reliable, and clinically useful psychiatric measures. Some of these are suitable for nonpsychiatrists to administer and should be considered for routine initial assessment, such as the Diagnostic Interview Schedule (DIS) (Helzer et al. 1990). While the Addiction Severity Index (ASI) is useful as a screening tool because it alerts staff to the possibility of a psychiatric disorder, a full diagnostic workup would still be indicated, as the ASI does not direct one to the treatment option of choice (McLellan et al. 1980).

Another source of treatment help is the burgeoning research in psychopharmacologic agents. New advances offer a greater range of treatment options for complex problems. Clinicians should understand that while some research initiatives have shown early promise for the psychopharmacologic agents mentioned below and elsewhere in the chapter, this promise has not yet translated into daily clinical usefulness. Furthermore, some of the regimens employing those agents use approved medication (e.g., clonidine) for nonapproved use (e.g., detoxification). The

clinician is advised that under these circumstances, full informed consent is needed and should be documented in the chart.

The antihypertensive drug, clonidine, has been proven in research arenas to be an effective adjunct for opiate detoxification (Kleber et al. 1985). This advance opens the door to other detoxification research, such as rapid opiate detoxification and transition to opiate blockade, using tapering doses of clonidine overlapped with increasing doses of naltrexone (Trexan). Methadone-maintained patients who are also dependent on short-acting benzodiazepines such as alprazolam (Xanax) may benefit from detoxifying with the less reinforcing, long-acting benzodiazepine, clonazepam (Klonopin), although further research is needed to optimize this approach in multidrug dependence (Pollack 1987). Patients with combined cocaine and heroin dependence may benefit from the long-acting opioid buprenorphine (Buprenex) according to preliminary studies by groups at Massachusetts General Hospital, McLean Hospital, and Yale University. These medications offer considerable promise, pending the outcomes of more definitive studies that are underway.

Implications of Multidrug Use for the Treatment Team

Other substance dependence among patients in MMTPs thus presents interesting management problems. The complexity of multisubstance abuse in particular demands a multidisciplinary model of treatment that attempts to take the best of the existing models of care and apply them to patients as dictated by assessment and followup.

The treatment team must consist of a number of individuals from different disciplines to give attention to the following areas of patient need: Health, education, psychotherapy, family therapy, coping skills, self-help, and spiritual guidance. Treatment teams should involve addictionologists, psychiatrists, psychologists, nurses, social workers, and other individuals, in addition to counselors.

An addictionologist is a physician, usually trained in a medical specialty or psychiatry, with subspecialty training, and preferably certification, in addictive disease. For multidrug users especially, treatment should include medically evaluating the patient, implementing triage, and determining where the patient belongs on the continuum of care. An addictionologist can provide long-term followup and management (including pharmacologic) of physical problems associated with chemical dependency. Nursing care is a related, necessary component to help assess acute changes that may represent other drug intoxication or withdrawal. Nurses in the medication station need to be aware of all associated pharmaceuticals taken by the patient and the presentation of adverse drug-drug interactions. Providing chemically dependent individuals with quality medical services is vital because these patients present with the highest rates of comorbid conditions, both physical and psychological, such as HIV infection or depression.

A psychiatrist usually is involved in performing in-depth evaluations of the individual, managing psychiatric medication, and in some cases providing psychotherapy. A subset of methadone-maintained patients will continue to use other drugs to self-medicate psychiatric or medical conditions. Examples include using alprazolam (Xanax) for panic disorder or various opiates for chronic back pain or headache. Evaluating such patients requires particular expertise, and referral to specialized psychopharmacologists or specialized chronic pain units may be necessary. Individuals with specific psychiatric symptoms, for example, depression, may discover by experimenting that certain drugs, such as cocaine, will ameliorate those symptoms but may lead to dependence. Treatment therefore requires diagnosis of the underlying symptoms and possibly a combination of pharmacotherapy and psychotherapy (see ch. 5).

A psychologist should be available to evaluate neuropsychiatric impairments, help the team articulate the patient's strengths and weaknesses, and provide primary therapy. The psychiatrist or psychologist also provides consultation to the treatment team. The primary counselor works with the patient to implement the treatment plan.

The treatment team should provide case management services to assist patients in changing their environment to reduce their risk of reexposure to drugs. These services could include helping the patient to move from a provocative home environment, helping an unemployed addict find a job or obtain job-related skills, and so forth. A social worker usually functions as a case manager on the treatment team.

Other needs include family therapy and spiritual counseling. A family therapist can help to heal the family's wounds caused by substance abuse and assist family members in making changes to support the patient's recovery as well as their own. Family resistance to the patient's recovery occurs to some extent, and this problem particularly can precipitate relapse with other drugs despite adequate

methadone maintenance treatment for opioids. A pastoral caregiver may assist the patient in identifying his or her spiritual needs, addressing those needs, and listening to the patient's fifth step in a 12-step program,[2] if that is part of the program prescribed for the patient.

Many methadone maintenance treatment programs, particularly those with limited resources, will not have all of these treatment providers, so some staff members will have numerous roles. For example, the counselor may coordinate the activities of the treatment team, manage the case, ensure that the treatment goals are met, and serve as the psychologist, the social worker, the pastoral caregiver, and the health advocate for the patient in some settings. However, these multiple roles may also dilute the counselor's effectiveness, heighten the patient's dependence on a single individual, and impede the patient's progress.

Heroin and Alcohol Interactions

Alcohol deserves special mention as a secondary drug of choice. Remarkably, in the past century, alcohol and heroin have been mistaken as potential treatments for one another (Siegel 1986), and iatrogenic dependence in both directions has been the result of these good intentions. The two drugs have some common analgesic effects; experimental evidence suggests that opioid antagonists (e.g., naltrexone) may diminish alcohol intoxication (Nyers et al. 1986), and opiate peptides or receptors may be modulated by alcohol use (Trachtenberg and Blum 1987). Animal studies indicate that alcohol use can produce increased methadone concentrations in the brain (Lane et al. 1985). Most importantly, alcohol and related drugs are CNS depressants that are potentiated by methadone and can produce coma and death in overdose. When correctly prescribed, disulfiram (Antabuse) is a viable option for an adjunctive management of alcohol use in the patient in an MMTP.

Much study over many years has shown that alcohol use patterns among patients do not change much over time. There are a subset of patients who do better in treatment and another subset whose problems worsen.

For alcoholic heroin addicts, retention in methadone maintenance treatment itself seems to offer some benefit. Stimmel and coworkers, in a 2.5-year prospective study, found no differential benefit of random assignment to each of three treatment regimens. The factor that correlated best with reduced alcohol consumption was length of time in methadone maintenance treatment (Stimmel et al. 1983). This outcome, however, says less about the efficacy of methadone maintenance treatment for alcoholism than it does about the lack of good treatments for comorbid heroin and alcohol dependence. There is virtually no literature on this complex issue, although suggestions have been offered, for example, that disulfiram (Antabuse) be considered as a tool for managing alcohol use by methadone maintenance patients who do not benefit from alcohol abstinence-oriented treatment (Joseph and Appel 1985). Alcohol dependence may become an even more critical issue following completion of methadone maintenance treatment, with studies indicating a number of patients becoming seriously ill with alcohol dependence, and even dying from cirrhosis, despite remaining opioid abstinent (Joseph and Appel 1985). There are other patients who, while attempting to undergo a gradual withdrawal from methadone, will switch to alcohol.

Heroin and Other Central Nervous System Depressant Interactions

Like alcohol, the other depressants pose increased risks for toxicity and overdose with methadone. Alcohol and CNS depressants can induce life-threatening withdrawal reactions, which are not treated by methadone. Signs and symptoms of withdrawal include elevated body temperature, hypertension, rapid pulse, confusion, hallucinations, and intractable seizure. When depressant drug dependence is diagnosed in the methadone-maintained patient, methadone should be continued (and the patient monitored for a possible need for an increase), and the depressant should be withdrawn as clinical circumstances dictate. Detoxification from depressants may require inpatient treatment to be effective, and methadone maintenance treatment should be continued during the inpatient stay. Additionally, a history of seizures during sedative-hypnotic-anxiolytic or alcohol withdrawal is an absolute indication for inpatient medically managed detoxification.

Heroin and Cocaine Interactions

Initial hopes that MMTPs would reduce cocaine use have been discarded on the basis of discouraging reports. A group from the San Francisco General Hospital found that 24 percent of patients began or increased cocaine use after beginning methadone maintenance treatment (Chaisson et al. 1989). Kosten and coworkers (1987) conducted a 2.5-year followup study that showed that the amount of cocaine use had been only minimally reduced by methadone maintenance, and the number of patients who used cocaine weekly actually doubled.

One reason that comorbid stimulant and opioid use is so prevalent is that the two drugs

counteract each others' side effects. This interaction accounts for the popularity of the heroin and cocaine combination known as "speedball." Heroin "mellows out" cocaine-induced agitation, while cocaine allows the addict to experience opioid euphoria without the "nod." The temporal relationship of other drug use (whether heroin or, for example, cocaine is the primary drug or drug of choice) is important in assessing the individual's needs. Primary cocaine addicts may need specific attention given to the cocaine dependence early in treatment. Clinical experience suggests that primary heroin addicts will not use cocaine prior to getting an adequate "fix" of heroin. Cocaine used alone causes sufficient agitation that the heroin addict may misperceive cocaine as precipitating opioid withdrawal when not pretreated with heroin.

Primary cocaine addicts, on the other hand, will use cocaine first and take heroin to ameliorate the adverse effects of the "crash." Primary cocaine addicts can, over time and given enough use of heroin, develop a physiologic dependence upon heroin and require methadone maintenance as treatment. It is not appropriate to deny a heroin addict treatment in a methadone maintenance program because of the presence of other addictions; a rational treatment plan that integrates measures for treating all psychoactive agents should be devised.

To date, there are no cocaine-specific treatment programs, although behavior modification techniques are under exploration. As stated earlier, a number of research initiatives on the so-called anticraving drugs showed early promise (tricyclic antidepressants, Ritalin, buprenorphine, etc.), but the promise has not yet translated into daily clinical usefulness.

Tricyclic antidepressants have been explored extensively (Gold et al. 1992; McElroy et al. 1989), but early results have not been replicated. At this time, tricyclics are a subject for further research and treatment of patients with these medications is in the research domain.

Policy Regarding Methadone Maintenance Treatment and Other Substance Abuse

In some States a historical separation of regulatory, certification, and funding processes between alcohol treatment and drug treatment has created barriers to treating patients who require both services. Where these systems have developed in parallel, patients tend not to cross service boundaries, despite need. Given a high frequency of alcohol dependence in methadone maintenance treatment centers, programs need to be able to provide alcoholism-related services either on-site or through referral. The method of delivering service proposed here involves cross-training staff in both systems, where dual systems exist. It is also necessary to educate primary alcoholism counselors about the role of methadone in treating heroin addiction to foster understanding and acceptance of the patients.

Fortunately, apart from the issue of alcohol services, a representative survey found that approximately 70 percent of MMTPs in the United States also treat drug problems other than heroin (D'Aunno and Vaughn 1992). This fact suggests that skills for treating other drug dependencies are available within a single agency to many methadone maintenance patients, though not to all. One possible problem unearthed by this survey is that programs providing methadone and other drug treatment tend to withdraw methadone maintenance patients earlier. This practice may reflect a contamination effect, whereby the drug-free strategy for other drug dependencies adversely influences longitudinal methadone maintenance treatment strategy. If this supposition is true, further education and policy clarification are needed to promote effective methadone maintenance treatment, since longer treatment is highly correlated with increased success (Hubbard et al. 1989).

Response to Multisubstance Use

The following guidelines can help to match the patient to services needed to treat multiple substance use. The intensity of treatment should be based on the needs of the patient and depends on the magnitude of change that a patient has to make in order to achieve and maintain abstinence from drugs (see ch. 3). A patient's past successes and future potential must be evaluated if change is to occur. For example, a patient who is employed, has a full range of social and emotional supports, is meeting more than just basic human needs, and is using a substance that is not readily available in his or her community has a better chance of achieving recovery in a less intense level of care than a homeless, HIV-infected young adult who has not completed high school and has never been employed. In order for the latter patient to reach recovery, he or she may require an environment where basic human needs are met (residential care) in order to attend treatment. This individual may need support until developing a plan for obtaining an education and employment and may also need to significantly change his or her social and environmental situations. The services delivered should reflect the intensity of the changes required.

Once the methadone-maintained patient is identified as having an additional substance use problem, several changes in treatment are possible. A survey of 11 Baltimore-area MMTPs identified several therapeutic measures that have varying degrees of efficacy (Kolar et al. 1990). It is essential for the credibility of the treatment program that the counselor confront the patient with the problem within days after the problem is identified (usually through a urine screen). After a pattern suggesting a problem emerges and further information is gleaned from the patient, significant other, family, or all three, two types of responses are possible. The first is increased support, in terms of treatment sessions, number of caregivers, and facilities. The second is intensified structure. Program evaluation should reveal a flexible combination of the two types of responses on the basis of individual patient need.

Intensified Support

When it is discovered that multisubstance abuse is occurring, the patient should begin receiving increased counseling, either individual or group or a combination of both. Group treatment should include a psychoeducational component, which may occur over 8–12 weeks and should cover the mechanisms of the other relevant substance dependencies, consequences, treatment techniques, and the risk of worsening dependence following methadone maintenance treatment. Some programs go beyond encouraging the patient to participate in a self-help group and actually require the patient to do so at this point.

Some patients may require the additional intensity of inpatient treatment. Despite the fact that this is available in few States, residential rehabilitation in conjunction with methadone maintenance or methadone stabilization is an essential resource. When offered, this level of care can be used for the very complex heroin user who has not been able to abstain from heroin or other drugs as an outpatient. Early demonstration programs of methadone maintenance involved an inpatient stay for initiating methadone maintenance. One of the benefits of the structured environment where access to heroin and other drugs is limited is that the individual may achieve abstinence faster than the individual who has methadone initiated as an outpatient.

Intensified surveillance is also justified at this point as a necessary means of helping to protect the patient from his or her disease. Addiction, unique among chronic illnesses in its power to distort self-perception, requires rigorous and frequent reality testing in order to help the patient recognize this danger. Programs should have objective policies concerning the increased frequency of urine toxicologies. One program in the Baltimore study reported charging patients for additional screenings invoked because of multisubstance use.

Intensified Structure

Intensified structure may take the form of setting greater limits on substance use behavior. For example, some programs reduce take-home methadone privileges, while others eliminate them. Behavior modification research suggests that a predictable, graduated, and achievable privilege schedule is most likely to meet with success. Contingency contracts at one point were recommended for cocaine-using patients, in particular, because of the extreme relapse compulsion experienced with this drug (Anker and Crowley 1982). The enthusiasm for this technique has waned. As indicated in chapter 5, contingency contracts should *not* involve methadone dose levels: Some clinics have imposed the counterproductive contract of reducing methadone doses in response to multidrug use. Inservice training of clinical staff is essential for appropriate use of contingency contracts, and attentive supervision is needed to ensure that constructive strategies are used rather than strictly punitive ones (Kolar et al. 1990).

The key to evaluating program adequacy here is to tally the techniques of intensified support against those of intensified structure and determine whether multisubstance-dependent patients receive a balanced diet of approaches. When patients feel that the clinic provides a fair set of treatment options, including the safe haven of inpatient detoxification from other drug dependence with ongoing methadone maintenance, they will accept and recognize the benefit of intensified surveillance. Alternatively, when they feel they have no place to go but out, they will invite this as a self-fulfilling prophecy.

Other Issues in Responding to Multisubstance Use

When patients have complicated medical needs, they need increased levels of medical management or supervision. Substances that pose a potential threat to an individual's life or the life of another (e.g., a fetus) and require detoxification need to be managed by a physician. In rare instances, this process can be accomplished in an outpatient setting; more often it must be done where there can be intense monitoring of the patient for early signs of deterioration in his or her medical condition.

Individuals taking large doses of sedative-hypnotic-anxiolytics or consuming large amounts of alcohol may not be able to abruptly stop their multiple substance use

without the assistance of a detoxification program. If there is any real gap in the service continuum for treating multiple substance use among individuals in MMTPs, it is for medically managed or supervised inpatient (or outpatient) detoxification in a setting where the methadone dose is maintained undisturbed. This service need should be a priority for State development. One of the core obstacles is that many detoxification programs view abstinence (including abstinence from methadone) as the only acceptable goal for all chemically dependent persons.

Patients who have failed at one level of care need a more intensive level of care. For example, a patient may continue to use substances in an outpatient setting and, as a result, will be unable to engage in outpatient counseling. In passively resisting outpatient treatment, the patient may even give the appearance of not needing intensive treatment. This type of patient, in particular, may require an inpatient treatment setting initially in order to establish abstinence. Once abstinence has been established, the patient may be able to move back into outpatient treatment.

Occasionally, it emerges that heroin is not the primary drug of choice in an individual and there have not been intense physiologic changes brought about by the use of heroin. In this event, providers need to reconsider the initial methadone maintenance treatment request and instead consider referral to residential rehabilitation and abstinence-oriented approaches (see ch. 3 and ch. 4).

Finally, people who have completed one intense level of care may not need to repeat the experience following a relapse. For example, some 28-day hospital-based program guidelines may recommend that individuals repeat treatment following a relapse to alcohol. A better response, however, may be medically managed detoxification followed by outpatient counseling to support sobriety for the individual who has made and sustained lifestyle changes. Individuals who have not made these changes, however, may need to be referred to a long-term therapeutic community for rehabilitation. What should be considered is whether the patient has a foundation upon which to build. Long-term residential rehabilitation combined with methadone maintenance is yet another option that deserves to be investigated and demonstrated, which will only occur with State and Federal support.

Summary

Multiple substance use within the context of methadone maintenance treatment can and should be addressed by programs on-site or through referral. A high prevalence of these disorders is indicated by numerous research reports, and morbidity and mortality are similarly high, even following apparently successful methadone maintenance treatment. The phenomenology and pharmacology of multidrug dependence are complex but comprehensible. Assessment must be more detailed than for opioid dependence alone. To some extent, a range of treatment options to address multisubstance use in methadone maintenance patients exists. These options are not well researched. They do, however, provide some clinical contribution beyond the simple relationship between staying in methadone maintenance treatment for some critical period and reduced frequency and severity of other substance use. States have a crucial leadership role to play in promoting investigation, an expanded range of treatment options, and greater resource flexibility by developing new policies and recognizing the long-term benefits of such efforts.

Recommendations

- In carrying out an assessment, distinguish between other substance use, abuse, and dependence and determine patterns of other drug use and self-reported etiologies, including nonprescribed, nontherapeutic use, and prescribed therapeutic use.
- Provide a variety of services that support cessation of nonprescribed substance use as the desired goal.
- Ensure that program objectives indicate that abstinence from other substance use should extend for increasing periods, progress toward long-term abstinence, and be associated with improved life functioning and well-being.
- Devise a rational treatment plan that integrates measures for treating all psychoactive agents.
- Educate patients about their vulnerabilities from cross-tolerance, drug-drug interaction and potentiation, dependency substitution, and self-medication.
- Ensure that program staff are instructed in the goals of methadone maintenance vis-à-vis alcohol and other drug use. If working in a program with on-site staff in nonmethadone treatment modalities, provide instruction and supervision to safely integrate methadone maintenance treatment principles with these modalities.
- Ensure that treatment options include a balance of intensified support and intensified structure in response to multisubstance use.
- Ensure that treatment options are extensive, are coordinated, and provide a continuum of care

across the boundaries of physical sites and programs.
- Develop demonstration and research on inpatient detoxification from other drug dependencies with continuity of methadone dose.

References

American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 3d ed., rev. Washington, DC: American Psychiatric Press, 1982.

Anker, A., and Crowley, T. Use of contingency contracts in specialty clinics for cocaine abuse. In: National Institute on Drug Abuse Treatment Research Monograph 41. Rockville, MD: U.S. Department of Health and Human Services, 1982, pp. 452–491.

Chaisson, R.E.; Bacchetti, P.; Osmond, D.; Brodie, B.; Sande, M.A.; and Moss, A.R. Cocaine use and HIV infection in intravenous drug users in San Francisco. *Journal of the American Medical Association* 261:561–565, 1989.

Criteria Committee, National Council on Alcoholism. Criteria for the diagnosis of alcoholism. *Annals of Internal Medicine* 77:249–258, 1972.

D'Aunno, T., and Vaughn, T.E. Variations in methadone treatment practices: Results from a national study. *Journal of the American Medical Association* 267:253–258, 1992.

Drug Abuse Warning Network: National Institute on Drug Abuse Annual Emergency Room Data. I(10-A). Rockville, MD, 1990. pp. 1–120.

DuPont, R.I., and Saylor, K.E. Marijuana and benzodiazepines in patients receiving methadone treatment (letter). *Journal of the American Medical Association* 261:3409, 1989.

Gold, M.S.; Miller, N.; Jonas, J.M. Cocaine and crack neurobiology. In: *Substance Abuse: A Comprehensive Textbook*. Williams and Wilkins, 1992. pp. 222–235.

Helzer, J.; Canino, G.; Yeh, E.; Bland, R.; Lee, C.; Hwu, H.; and Newman, S. Alcoholism—North America and Asia: A comparison of population surveys with the Diagnostic Interview Schedule. *Archives of General Psychiatry* 47:313–319, 1990.

Hubbard, R.L.; Marsden, M.E.; Fachas, J.V.; Harwood, H.J.; Cavanaugh, E.R.; and Ginzburg, H.M. *Drug Abuse Treatment: A National Study of Effectiveness*. Chapel Hill: University of North Carolina Press, 1989.

Jaffe, J.H. Drug addiction and drug abuse. In: Goodman, L.S., and Gilman, A.G., eds. *The Pharmacological Basics of Therapeutics*. New York: MacMillan Publishing Co., 1975. pp. 284–92.

Jellinek, E.M. *Disease Concept of Alcoholism*. New Haven, CT: United Printing Service, 1960.

Joseph, H., and Appel, P. Alcohol and methadone treatment: Consequences for the patient and program. *American Journal of Drugs and Alcohol Abuse* 11:37–53, 1985.

Kleber, H.; Riordan, C.; Rounsaville, B.; Kosten, T.; Chyarney, D.; Gaspari, J.; Hogan, I.; and O'Connor, C. Clonidine in outpatient detoxification from methadone maintenance. *Archives of General Psychiatry* 42:391–394, 1985.

Kolar, A.F.; Brown, B.S.; Weddington, W.W.; and Ball, J.C. A treatment crisis: Cocaine use by clients in methadone maintenance programs. *Journal of Substance Abuse Treatment* 7:101–107, 1990.

Kosten, T.; Kleber, H.; and Morgan, C. Treatment of cocaine abuse with buprenorphine. *Biology of Psychiatry* 26:637–639, 1989.

Kosten, T.R.; Rounsaville, B.J.; and Kleber, H.D. A 2.5-year follow-up of cocaine use among treated opioid addicts: Have our treatments helped? *Archives of General Psychiatry* 44:281–284, 1987.

Lane, E.A.; Guthrie, S.; and Linnoila, M. Effects of ethanol on drug and metabolite pharmacokinetics. *Clinical Pharmacokinetics* 10:228–247, 1985.

Ling, W.; Weiss, D.G.; Charuastra, V.C. Use of disulfiram for alcoholics in methadone programs. *Archives of General Psychiatry* 40:851–854, 1983.

McElroy, S.L.; Weiss, R.E.; Mendelson, J.H.; Teoh, S.K.; McAfee, B.; Mello, N.K. Desipramine treatment for relapse prevention in cocaine dependence. In: *Proceedings of 51st Annual Scientific Meeting of Committee on Problems of Drug Dependence*. National Institute on Drug Abuse Research Monograph 95. Rockville, MD: U.S. Department of Health and Human Services, 1989.

McLellan, A.; Luborsky, L.; and Woody, G. An improved evaluation instrument for substance abuse patients: The Addiction Severity Index. *Journal of Nervous and Mental Disorders* 168:26–33, 1980.

Mello, N.; Mendelson, J.; Bree, M.; and Lukas, S. Buprenorphine suppresses cocaine self-administration by rhesus monkeys. *Science* 245:859–862, 1989.

Nyers, R.D.; Borg, S.; and Mossberg, R. Antagonism by naltrexone of voluntary alcohol selection in the chronically drinking macaque monkey. *Alcohol* 3:383–388, 1986.

Pollack, M. Clonazepam: A review of open clinical trials. *Journal of*

Clinical Psychiatry 48 (supp.):12–15, 1987.

Primm, B. Plenary session, December 1990, Office for Treatment Improvement First Technical Assistance Meeting. Bethesda, MD: Office for Treatment Improvement, 1990.

Rounsaville, B.; Anton, S.; Carroll, K.; and Budde, D. Psychiatric diagnoses of treatment-seeking cocaine abusers. *Archives of General Psychiatry* 48:43–51, 1991.

Siegel, S. Alcohol and opiate dependence: Re-evaluation of the Victorian perspective. *Research Advances in Alcohol and Drug Problems* 9:279–314, 1986.

Stimmel, B.; Cohen, M.; Sturiano, V.; Hanbury, R.; Korts, D.; and Jackson, G. Is treatment for alcoholism effective in persons on methadone maintenance? *American Journal of Psychiatry* 140:862–866, 1983.

Trachtenberg, M.C., and Blum, K. Alcohol and opioid peptides: Neuropharmacological rationale for physical craving of alcohol. *American Journal of Drug and Alcohol Abuse* 13:365–372, 1987.

Vaillant, G. A twelve-year follow-up of New York narcotic addicts: Some characteristics and determinants of abstinence. In: Shaffer, H., and Burglass, M.E., eds. *Classic Contributions in the Addictions*. New York: Brunner/Mazel, 1981.

Vaillant, G. Natural history of male alcoholism: Is alcoholism the cart or the horse to sociopathy? *British Journal of Addictions* 78:317–326, 1983.

Endnotes

1. Case example: A chronic heroin addict in methadone maintenance treatment for 2 years with severe alcohol and benzodiazepine abuse and occasional heroin use complained that his 140-mg dose was "not holding." Blood levels were found to be 139 ng/ml at 3 hours and 76 ng/ml at 24 hours. After increasing the dose to 180 mg, concurrent substance use subsided.

2. The fifth step in a 12-step program is "Admitted to God, to ourselves, and to another human being the exact nature of our wrongs."

Chapter 9—Methadone Maintenance During Pregnancy

Karol Kaltenbach, Ph.D.
Neil Silverman, M.D.
Ronald Wapner, M.D.

Since the early 1970s, methadone maintenance has been recommended for narcotic dependency in pregnancy (Blinick et al. 1973). In addition to the benefits provided by methadone maintenance treatment described elsewhere in these guidelines, the use of methadone as a maintenance therapy for the pregnant woman provides the advantages of preventing erratic maternal opioid drug levels and protecting the fetus from repeated episodes of withdrawal. A comprehensive MMTP that includes prenatal care can reduce the incidence of obstetrical and fetal complications, in utero growth retardation, and neonatal morbidity and mortality (Finnegan 1991). Additionally, maternal nutrition is usually improved and exposure to HIV through ongoing needle use can be reduced. Comprehensive services also enable women to engage in social-psychological rehabilitation and prepare for the birth of the child (Finnegan 1991).

However, methadone maintenance treatment during pregnancy is not without controversy, especially with regard to medical withdrawal, appropriate dose levels, and severity of neonatal abstinence syndrome (AS). Perinatal and developmental outcomes of infants exposed to methadone in utero have also been areas of concern.

Diagnosing Narcotic Addiction

On the basis of medical and substance abuse history, as well as physical examination, the diagnosis of opioid addiction in the pregnant opioid-dependent person is similar to that in a nonpregnant opioid-dependent person and includes urine toxicologies and early signs and symptoms of withdrawal. Other factors may provide additional evidence, such as diseases associated with drug use (e.g., hepatitis, bacterial endocarditis, or cellulitis), poor attendance for prenatal care, unexplained fetal growth, abnormalities (intrauterine growth retardation), or failure to have prenatal laboratory work performed because of a lack of available veins.

It must be emphasized that using narcotic antagonists to diagnose heroin dependence in pregnancy is absolutely contraindicated. Inducing even mild withdrawal may result in adverse fetal effects.

Medical and Obstetrical Issues

In general, all pregnant women who are substance abusers are considered to be in a higher-than-normal risk category because of the complications of alcohol and other drug use. The early signs of pregnancy, such as fatigue, headaches, nausea and vomiting, and cramps, in fact, may be interpreted as withdrawal symptoms by both physician and patient. Frequently, the onset of these symptoms compels the opioid-dependent woman to use additional drugs that not only are ineffective in alleviating her symptoms but also expose the fetus to increased serum levels of narcotics and other drugs.

Chronic parenteral substance abuse during pregnancy has a variety of concomitant obstetrical and medical complications, depending on what method is used to administer drugs, whether reduced availability of drugs causes withdrawal, and whether prenatal care is used to identify and treat problems. Medical complications associated with drug use are listed in table 1. Infections account for a high percentage of related medical complications, and they may have profoundly harmful effects on the pregnant opioid-dependent woman and her unborn child, particularly if they remain unrecognized and untreated throughout gestation. Especially frequent are types A, B, and C hepatitis, bacterial endocarditis, septicemia, cellulitus, and STDs (Blinick et al. 1969; Cherubin 1971; Cherubin et al. 1972*a*; Cherubin and Millian 1968; Cherubin et al. 1972*b*; Cherubin et al. 1976; Cushman and Grieco 1973; Naeye et al. 1973).

Obstetrical complications in opioid-dependent women are those seen at increased rates in any

Table 1. Medical Complications of Drug-dependent Women That May Be Identified and Treated During Pregnancy

Complications	
Anemia	STDs
Bacteremia/septicemia	Chlamydia
Cardiac disease, especially endocarditis	Condyloma acuminatum
Cellulitis	Gonorrhea
Diabetes mellitus	Herpes
Edema	HIV
Hepatitis, acute and chronic	Syphilis
Hypertension	Tetanus
Phlebitis	TB
Pneumonia	Urinary tract infections
Poor dental hygiene	Cystitis
	Pyelonephritis
	Urethritis

Table 2. Obstetrical Complications That May Occur More Frequently Among Drug-dependent Women

Complications	
Spontaneous abortion	Placental insufficiency
Intrauterine death	Intrauterine growth retardation
Abruptio placentae	Premature rupture of membranes
Amnionitis	Premature labor
Choriamnionitis	Postpartum hemorrhage
Septic thrombophlebitis	Preeclampsia

women lacking prenatal care and are listed in table 2. Diagnosis of these complications can frequently be delayed because the patient denies that they exist or consciously avoids a threatening medical environment. Once these are confirmed, however, standard obstetrical treatment, including the use of medications to arrest preterm labor, can safely be initiated.

Methadone maintenance by itself is not necessarily sufficient to reduce perinatal complications but must be offered in conjunction with prenatal care reinforced by psychosocial counseling. Within the framework of a comprehensive program, complications can be identified and treated, thereby reducing maternal and infant morbidity and mortality.

HIV Infection

Because of unsafe sexual practices and needle sharing, the drug-dependent woman is at high risk for HIV infection. Participating in methadone maintenance can eliminate the danger of infection from contaminated needles, while HIV counseling and education provided within the treatment milieu can change sexual behavior patterns (Ball et al. 1988; Hubbard et al. 1989). It has also been reported that long-term maintenance reverses the decline in cellular immunity associated with injecting heroin (Novick 1989).

The provision of HIV counseling in a setting aligned with, but not linked to, prenatal care, in a medically "neutral" environment, has been shown to increase acceptance of HIV testing among women at the highest risk for infection (Silverman and Weiner 1992). Testing is of paramount importance in decreasing the escalating rates of perinatal transmission of HIV. According to the estimates by the National Association of Children's Hospitals and related institutions, about 3,000 infants are infected with the AIDS virus each year. Over 80 percent of children who become HIV-infected are born to drug-using women or women who have a sexual partner involved in substance abuse. Comprehensive methadone maintenance treatment programs for pregnant IV-drug-dependent women are essential to reducing or eliminating the perinatal transmission of HIV infection. As shown in a recent survey-based study, while opiate-addicted women do have general knowledge of HIV risk factors, current educational efforts have not resulted in a willingness to apply this information to assess their own risk status. Aggressive HIV educational efforts, in conjunction with narcotics abstinence support, therefore, are necessary to decrease risks of HIV infection both to these women and to their offspring (Silverman et al. in press).

Methadone Maintenance During Pregnancy

The pharmacology of methadone in the pregnant woman has been well evaluated. It is widely distributed throughout the body after oral ingestion, with extensive nonspecific tissue binding creating reservoirs that release unchanged methadone back into the blood, thus contributing to its long duration of action (Dole and Kreek 1973). After a maintenance dose of methadone is ingested, peak plasma levels occur between 2 and 6 hours, with less than 6 percent of the ingested dose in the total blood volume at this time (Inturrisi and Verebey 1972; Kreek 1973; Sullivan and Blake 1972). Lower sustained plasma concentrations are present during the remainder of the 24-hour period. Methadone is metabolized primarily by the liver

and excreted in the urine and feces both as unchanged methadone and a variety of metabolites.

Studies of methadone in pregnant women show marked intraindividual and interindividual variations, with a plasma level somewhat lower after a given dose during pregnancy than following delivery. This decrease in available methadone can be accounted for by an increased fluid space, a large tissue reservoir for storing methadone, and drug metabolism by both the placenta and the fetus (Kreek et al. 1974). **It is extremely important to understand the increases in blood volume and metabolic changes specific to pregnancy, as methadone-maintained women frequently develop increasing signs and symptoms of withdrawal as pregnancy progresses and need elevations of their oral dose in order to maintain the same plasma level and remain withdrawal free** (Finnegan and Wapner 1987).

Withdrawal from Methadone

While there is no evidence that methadone has an adverse effect on the pregnant woman, the efficacy of withdrawal from methadone during pregnancy remains an issue of debate. The most widely accepted recommendation (Finnegan 1991) is that if withdrawal is elected, it is not advised before 14 weeks gestation because of the potential risk of inducing abortion and should not be performed after the 32d week of pregnancy because of possible withdrawal-induced fetal stress. Withdrawal should be conducted under the supervision of physicians experienced in perinatal addiction and should ideally occur under the guidance of a perinatal unit equipped with fetal monitoring so that it can be discontinued if it causes fetal stress or threatens the onset of preterm labor. Withdrawal should be performed by decreasing the dose by no more than 5 mg every 1–2 weeks.

Occasionally patients who have been maintained on a relatively high dose of methadone or who have required large doses of methadone for the acute control of withdrawal symptoms will become pregnant. Again, withdrawal is not recommended during gestation, since the risks of withdrawal and recidivism associated with withdrawal are higher than any that might theoretically be associated with a "high" dose of a licit medication such as methadone.

Methadone Dose and Management

Drug-dependent women receiving methadone maintenance prior to pregnancy can initially be maintained on their prepregnancy dose. Opioid-dependent pregnant women who have not been maintained on methadone previously should be admitted to a hospital (the average stay is 3 days) to evaluate their prenatal health status, document physiologic dependence, and initiate methadone maintenance. An initial dose of 10–20 mg/day is usually given on the basis of the patient's prior substance use history, followed by individualized dosage adjustments based on patient responses. Additional 5-mg doses are given every 4–6 hours if withdrawal symptoms are manifested. On day 2, the previous day's total dose is administered as the new maintenance dose. Supplemental dose increases are given as needed if withdrawal symptoms persist. Most patients are able to be well controlled on a daily dose between 20 and 35 mg after the first 48–72 hours of maintenance. However, most patients will require a 10–30-mg increase during the course of pregnancy. Federal regulations state that pregnant women should be maintained on the lowest "effective" dose. The same criteria used to determine the appropriate maintenance dose in other patients are also applied to opioid-dependent pregnant women: The desired clinical effects should include prevention of AS, reduction or elimination of drug craving, and blockade of the euphoric effect of narcotics (Kreek 1987). Depending on the duration of her addiction, the duration on methadone maintenance, individual metabolic rates, and the presence of concomitant drugs, such as anticonvulsant medications, the "lowest possible dose" may vary from 35 mg to 80 mg. Each woman should have her dose individualized in conjunction with continuing appropriate monitoring of the pregnancy (Finnegan 1991).

Because of the frequent need to increase methadone dose in the third trimester due to altered metabolism of methadone in the later stages of pregnancy, there has been some attention directed toward splitting the dose in order to facilitate steady-state maintenance. However, to date, only one study involving seven patients (Whittman and Segal 1991) has attempted to evaluate differences in fetal activity as a function of single-dose or split-dose methadone maintenance treatment regimes. Although the split-dose regime may be effective, it requires further investigation before recommendations are warranted.

Overdose

Occasionally, patients will present for scheduled methadone medication while objectively intoxicated from ongoing substance use. In such cases, to avoid overmedication or overdose or both, the patient's scheduled dose of methadone may be delayed until diminished intoxication symptoms

can be documented. Rather than withholding methadone on an absolute basis, however, it may be prudent to readmit such patients to observe them for withdrawal symptoms while augmenting their daily dose in a controlled, observable fashion.

Neonatal Abstinence in Methadone-Exposed Infants

Some of the most emotional negative reactions to the use of methadone with pregnant women result from the opinion that it increases the incidence and severity of neonatal abstinence. Infants prenatally exposed to heroin or methadone have a high incidence of neonatal abstinence. Neonatal abstinence is described as a generalized disorder characterized by signs and symptoms of central nervous system hyperirritability, gastrointestinal dysfunction, respiratory distress, and vague autonomic symptoms that include yawning, sneezing, mottling, and fever. The onset of withdrawal symptoms varies from minutes or hours after birth to 2 weeks of age, but the majority of symptoms appear within 72 hours. Many factors influence the onset of abstinence in individual infants, including the types of substances used by the mother, both the timing and the dose before delivery, the character of labor, the type and amount of anaesthesia analgesic given during labor, the maturity and nutrition of the infant, and the presence of intrinsic disease in the infant. The withdrawal syndrome may be mild and transient, may be delayed in onset or have a stepwise increase in severity, may be intermittently present, or may have a biphasic course that includes acute neonatal withdrawal signs, followed by improvement and then the onset of a subacute withdrawal reaction (Desmond and Wilson 1975).

While abstinence may be more severe and/or prolonged with methadone than heroin because of the longer half-life of methadone, with appropriate pharmacotherapy, neonatal abstinence can be satisfactorily treated without any untoward neonatal effects. It is recommended that an abstinence scoring system be used to monitor the passively addicted neonate in a comprehensive and objective way to assess the onset, progression, and diminution of symptoms of abstinence (Finnegan 1990). The score is used to monitor the infant's clinical response to pharmacotherapeutic intervention necessary for the control of abstinence symptoms as well as for detoxification.

Because some studies have shown that the degree of neonatal withdrawal may be correlated with maternal methadone dose in the last trimester of pregnancy, low-dose maintenance at <20 mg has sometimes been recommended. However, the relationship between maternal methadone dose and the presence of withdrawal symptoms has been difficult to establish. Ostrea and coworkers (1976) and Madden and coworkers (1977) both reported a significant relationship between severity of withdrawal and methadone dose during pregnancy. Other investigators (Blinick et al. 1973; Rosen and Pippenger 1975; Stimmel et al. 1982–83) found no relationship between severity of withdrawal and maternal methadone dose. Kaltenbach and coworkers (1990) examined maternal methadone doses during pregnancy and infant outcomes for 147 women maintained on low doses (5–40 mg), moderate doses (41–60 mg) or high doses (60 mg) of methadone during pregnancy. They found no differences between groups for number of days the infant required medication for abstinence, birth weight, or gestational age. Multiple regression analysis was used to determine factors predicting gestational age, birth weight, or days on medication for abstinence. There was no significant association for polysubstance abuse, narcotic use, use of drugs other than opiates, average methadone dose, total months on methadone, or sex of the infant.

Neurobehavioral Characteristics

The neurobehavioral characteristics of newborns undergoing abstinence uniformly have been investigated using the Brazelton Neonatal Behavioral Assessment Scale (Brazelton 1973). A number of researchers (Chasnoff et al. 1984; Jeremy and Hans 1985; Kaplan et al. 1976; Strauss et al. 1975; Strauss et al. 1976) have consistently found that the behavior of infants born to opioid-dependent women differs from that of infants born to non-drug-dependent women. Narcotic-exposed infants have been found to be more irritable and less cuddly and to exhibit more tremors and have increased tone. Several studies also report that narcotic-exposed infants are less responsive to visual stimulation; moreover, it has been found that infants undergoing abstinence are less likely to maintain an alert state, so the orientation tasks used in the Brazelton assessment often are not able to be completed. Strauss and coworkers (1975) report that, when elicited, the orientation behavior of infants exposed to narcotics was comparable to that of non-drug-exposed infants.

An important aspect of these neonatal behavioral characteristics is their implications for mother-infant interaction. These infants are frequently difficult to nurture because of the behavioral changes, resulting in poor

mother-infant bonding. Hoegerman and coworkers (1990) suggest that the effects of these behavioral changes on mother-child bonding may be the most pervasive and devastating legacy of perinatal addiction. However, within a comprehensive treatment program targeting the mother-child dyad during the perinatal and infancy periods, these consequences can be ameliorated by using appropriate intervention and education strategies designed to improve mother-infant interaction and by providing emotional support from peers and professionals in parent-support groups.

If not contraindicated by risks associated with alcohol and illicit drug use, breast-feeding should be encouraged in methadone-maintained women because it improves mother-infant bonding and allows favorable immunologic factors to be transferred via breast milk. One contraindication to breast-feeding is ongoing use of alcohol and illicit drugs. Many substances, such as ethanol, amphetamines, and opiates, attain significant levels in breast milk. Methadone itself has been reported to reach an average milk:plasma ratio of 0.83 (Blinick et al. 1975), and in fact, in infants born to well-stabilized methadone-maintained mothers, breast-feeding may prevent withdrawal symptoms. Breast-feeding longer than 6 months, however, is probably not advisable because of the increasing quantity of milk that the larger infant ingests.

A second contraindication to breast-feeding is the risk of infection in past or current illicit-drug-using mothers. HIV infection has been shown to be transmissible via breast milk, and HIV-positive mothers should be counseled not to breast-feed their newborns. In addition, substance addiction is a risk factor for the newly discovered hepatitis C virus (HCV), previously categorized as non-A, non-B hepatitis. While data surrounding HCV transmission remain controversial, HCV-antibody-positive women should probably also be counseled against breast-feeding.

Perinatal and Developmental Outcome

Intrauterine growth of infants born to women maintained on methadone has also been an area of concern. A number of prospective studies have yielded somewhat inconsistent findings. Studies that have compared infants born to heroin-dependent women not maintained on methadone with infants born to heroin-dependent mothers receiving methadone have found differential effects, with greater birth weights for infants born to methadone-maintained women (Connaughton et al. 1977; Kandall et al. 1977). Some studies that have compared methadone-exposed infants with non-drug-exposed infants found methadone-exposed infants to have lower birth weights than comparison infants (Chasnoff et al. 1982; Lifshitz et al. 1983), while others found no differences in birth weights (Rosen and Johnson 1982; Strauss et al. 1976). Smaller head circumferences among methadone-exposed infants have also been reported. A more recent study by Kaltenbach and Finnegan (1987) with a large sample of infants ($n = 268$) found methadone-exposed infants to have smaller birth weights and head circumferences than comparison infants. Although differences were found between the two groups, the methadone-exposed infants were not small for gestational age and there was a positive correlation between head circumference and birth weight for both the methadone-exposed infants and comparison infants ($r = 0.72$ and 0.69, respectively). The data from this study suggest that infants born to opioid-dependent women maintained on methadone during pregnancy may have smaller birth weights and head circumferences than non-drug-exposed comparison infants, but they are not growth retarded.

A longitudinal study by Pasto and coworkers (1989) evaluated the cerebral sonographic characteristics of methadone-exposed infants and comparison infants at birth, 1 month, and 6 months of age. Sonographic characteristics of the cerebral ventricles (slitlike, that is, no visible fluid, versus normal) were recorded, as well as transverse measurements of the intracranial hemidiameter (ICHD), right and left lateral ventricles, and temporal lobe, and thalamic area measurements (traced in a transaxial view). Methadone-exposed infants had significantly more slit ventricles at all three examinations, although the number of infants with slit ventricles decreased with age. At birth and 1 month of age, ICHDs were smaller in the narcotic-exposed infants, but thalamic area and temporal lobe measurements did not differ at any time. Methadone exposure in utero was highly associated with slit ventricles and was slower to resolve in lower birth weight infants. The smaller ICHD and lateral ventricle measurements were suggested to be possible markers of slower cortical growth.

The incidence of strabismus has been found to be greater in infants exposed to narcotics in utero than in the general population. A study by Nelson and coworkers (1987) of 29 narcotic-exposed infants found a 24 percent incidence of strabismus, in contrast to 5–8 percent incidence in the general population. Birth weights were lower for the infants with strabismus ($p = 0.05$), but average maternal methadone dose during pregnancy was higher, so

whether strabismus was related to lower birth weight, narcotic exposure, or a combination of factors is unclear.

Diverse findings between studies reflect the myriad of confounding variables that are present within human populations. The women differ on amounts of daily methadone dose, length of methadone maintenance during pregnancy, and amount of prenatal care. A large percentage of pregnant women maintained on methadone continue to use a number of other drugs, such as heroin, diazepam, cocaine, and barbiturates. In addition, 90 percent are moderate to heavy smokers, and alcohol consumption is quite prevalent (Rosen and Johnson 1982; Wilson et al. 1981).

Developmental sequelae associated with in utero methadone exposure have also been investigated in a number of longitudinal studies. A study by Strauss and coworkers (1976) found both methadone-exposed infants and comparison infants to score well within the normal range of development on the Bayley Mental Development Index (MDI) and the Motor Development Index (PDI) at 3, 6, and 12 months of age. However, PDI scores for the methadone-exposed infants declined with age and differed from comparison infants at 12 months of age. Wilson and coworkers (1981) also found no difference in MDI scores among the infants they studied at 9 months of age but found lower PDI scores for the methadone-exposed infants. While Rosen and Johnson (1982) found no difference between groups for MDI and PDI scores at 6 months of age, they found methadone-exposed infants to have both lower MDI and PDI scores at 12 and 18 months of age. In comparison, Lodge (1977) found no difference between groups for either the MDI or PDI at 6 and 12 months of age; Hans and Jeremy (1984) reported no difference at 4, 8, and 12 months of age; Kaltenbach and Finnegan (1986) found no difference at 6, 12, and 24 months of age; and Chasnoff and coworkers (1984) reported no difference at 3, 6, 12, and 24 months of age. Although neonatal abstinence and the concomitant neurobehavioral characteristics may be directly attributed to in utero methadone exposure, further delineation of the effects of prenatal methadone exposure is a very difficult and complex task.

Elucidating the developmental outcomes of children exposed to methadone in utero cannot be accomplished solely by using outcome measures representative of the studies that have been accomplished over the last two decades. If we are to fully understand the development of children exposed to methadone in utero, maternal characteristics of drug-dependent women must also be investigated to determine if there are specific environmental risk factors concomitant to this population. Maternal personality traits, degrees of life stress, patterns of child care, and the qualitative characteristics of mother-child interaction are variables that need to be examined. It may well be that the prenatal exposure to methadone is one of the least important risk factors for infants born to drug-dependent women maintained on this medication (Kaltenbach and Finnegan 1984).

Comprehensive Services

Appropriate treatment services for pregnant opioid-dependent women must be comprehensive and should include individual, group, and family therapy and address not only the physiological and psychological effects of substance use but the impact of sociological factors. Treatment must respond to the numerous medical and social variables that complicate addiction issues and recovery. Problems associated with domestic violence, support, food, housing, and child care may be overwhelming to the recovering drug-dependent woman. Relapse is imminent when daily survival is at risk. AIDS prevention, counseling, and testing and educational services in the form of prenatal and parenting classes should be available. Services should be aimed at eliminating substance use, developing personal resources, improving family and interpersonal relationships, reducing and eliminating socially destructive behavior, and facilitating maximum obtainable adaption for new parents within their environment. If methadone maintenance is combined with medical, psychological, and sociological treatment components, it is possible to markedly improve maternal and infant outcomes (Finnegan et al. 1991).

Summary

It is essential that the use of methadone maintenance during pregnancy be viewed within an appropriate context. Methadone is a licit drug used to treat a chronic relapsing disease and, as with any treatment drug, the risk-benefit ratio must be considered. When methadone maintenance treatment is provided for pregnant drug-dependent women within a comprehensive treatment program that addresses the medical, obstetrical, psychosocial, and addiction issues, maternal and infant morbidity and mortality are reduced, and the developmental and cognitive functioning of the progeny is not impaired.

Recommendations

- Base the diagnosis of opioid addiction in the pregnant opioid-dependent woman on the

same factors (e.g., medical and substance abuse history, psychosocial history, physical examination, urine toxicologies, signs and symptoms of withdrawal, etc.) that are used in diagnosing opioid addiction in nonpregnant opioid-dependent women, making sure to avoid the use of narcotic antagonists.

- Provide methadone maintenance for pregnant women within a comprehensive treatment program that addresses medical, prenatal, obstetrical, psychosocial, and addiction issues.
- When withdrawal from methadone is the selected option, conduct it under the supervision of a physician experienced in perinatal addiction, ideally in a perinatal unit equipped with fetal monitoring equipment; withdrawal *should not be* initiated before 14 weeks gestation *or* after the 32d week of pregnancy; always avoid symptoms of withdrawal during pregnancy.
- Initially maintain pregnant women on their prepregnancy methadone dose; it is advisable to admit nonmaintained pregnant women to a hospital (for an average of 3 days) to evaluate their prenatal health status, evaluate fetal growth, document physiologic dependence, and initiate methadone maintenance.
- Monitor pregnant women and individualize their dosages as needed. Elevate the oral dose of methadone if needed during the later stages of pregnancy to maintain the same plasma level and avoid withdrawal.
- Delay the administration of methadone to objectively intoxicated patients until diminution of intoxification symptoms can be documented, or readmit such patients to observe them for withdrawal symptoms while augmenting their daily dose in a controlled, observable fashion.
- Provide access to HIV testing and aggressive HIV counseling and educational efforts in conjunction with narcotic abstinence support to decrease the risks of HIV infection among pregnant women, their partners, and their offspring.
- Use an abstinence scoring system to monitor passively addicted neonates in a comprehensive and objective way to assess the onset, progression, diminution of abstinence symptoms, and to monitor effectiveness of treatment agents.
- Provide appropriate interventions, including education strategies and parent support groups, to improve the mother-infant interaction and lessen the behavioral consequences of poor mother-infant bonding.
- Breast-feeding may be encouraged during methadone maintenance treatment. However, if the patient is HIV positive or using multiple substances, breast-feeding is contraindicated.

References

Ball, J.C.; Lange, W.R.; Myers, C.P.; and Friedman, S.R. Reducing the risk of AIDS through methadone maintenance treatment. *Journal of Health and Social Behavior* 29:214–226, 1988.

Blinick, G.; Inturris, C.E.; Jerez, E.; and Wallach, R.C. Methadone assays in pregnant women and their progeny. *American Journal of Obstetric Gynecology* 121:617–621, 1975.

Blinick, G.; Jerez, E.; and Wallach, R.C. Methadone maintenance, pregnancy, and progeny. *Journal of the American Medical Association* 225:477, 1973.

Blinick, G.; Wallach, R.C.; and Jerez, E. Pregnancy in narcotic addicts treated by medical withdrawal. *American Journal of Obstetrics and Gynecology* 105:997, 1969.

Brazelton, T.B. *Neonatal Behavior Assessment Scale.* Philadelphia: Lippincott, 1973.

Chasnoff, I.J.; Hatcher, R.; and Burns, W. Polydrug and methadone addicted newborns: A continuum of impairment? *Pediatrics* 70:210, 213, 1982.

Chasnoff, I.J.; Schnoll, S.H.; Burns, W.J.; and Burns, K. Maternal non-narcotic substance abuse during pregnancy: Effects on infant development. *Neurobehavioral Toxicology and Teratology* 6(4):277–280, 1984.

Cherubin, C.E. Infectious disease problems of narcotic addicts. *Archives of Internal Medicine* 128:309, 1971.

Cherubin, C.E.; Kane, S.; Weinberger, D.R.; Wolfe, E.; and McGinn, T.G. Persistence of transaminase abnormalities in former drug addicts. *Annals of Internal Medicine* 76:385, 1972*a*.

Cherubin, C.E.; and Millian, S.J. Serological investigations in narcotic addicts. I. Syphilis, lymphogranuloma venereum, herpes simplex and Q fever. *Annals of Internal Medicine* 69:739, 1968.

Cherubin, C.E.; Rosenthal, W.S.; Stenger, R.E.; Prince, A.M.; Baden, M.; Strauss, R.; and McGinn, T.G. Chronic liver disease in asymptomatic narcotic addicts. *Annals of Internal Medicine* 76:391, 1972*b*.

Cherubin, C.E.; Schaefer, R.A.; Rosenthal, W.S.; McGinn, T.G.; Forte, F.; Purcell, R.; and Walmsley, P. The natural history of liver disease in former drug users. *American Journal of Medical Science* 272:244, 1976.

Connaughton, J.F.; Reeser, D.; and Finnegan, L.P. Pregnancy complicated by drug addiction. In: Bolognese, R., and Schwartz, R., eds. *Perinatal Medicine.*

Baltimore: Williams & Wilkins, 1977.

Cushman, P; and Grieco, M.H. Hyperimmunoglobulinemia associated with narcotic addiction: Effects of methadone maintenance treatment. *American Journal of Medicine* 54:320, 1973.

Desmond, M.M., and Wilson, G.S. Neonatal abstinence syndrome, recognition and diagnosis. *Addictive Diseases* 2:113–121, 1975.

Dole, V.P., and Kreek, M.J. Methadone plasma level: Sustained by a reservoir of drug in tissue. *Proceedings of the National Academy of Sciences* 70:10, 1973.

Finnegan, L.P., and Wapner, R.J. Narcotic addiction in pregnancy. In: Neibyl, J.R., ed. *Drug Abuse in Pregnancy*. Philadelphia: Lea & Febiger, 1987, pp. 203–222.

Finnegan, L.P. Neonatal abstinence syndrome. In: Nelson, N.M., ed. *Current Therapy in Neonatal-Perinatal Medicine*. Philadelphia: B.C. Becker, Inc., 1990.

Finnegan, L.P. Treatment issues for opioid-dependent women during the perinatal period. *Journal of Psychoactive Drugs* 23(2):191–201, April–June 1991.

Finnegan, L.P.; Hagan, T.A.; and Kaltenbach, K. Opioid dependence: Scientific foundations of clinical practice. In: *Pregnancy and Substance Abuse: Perspectives and Directions: Proceedings of the New York Academy of Medicine* 67(3):223–239, May–June, 1991.

Hans, S.L., and Jeremy, R.J. Post-neonatal motoric signs in infants exposed in utero to methadone. Paper presented at the Fourth International Conference on Infant Studies, New York, 1984.

Hubbard, R.L.; Marsden, M.E.; Rachal, J.V.; Harwood, H.J.; Cavanaugh, E.R.; and Ginzburg, H.M. *Drug Abuse Treatment: A National Study of Effectiveness*. Chapel Hill: University of North Carolina Press, 1989.

Hoegerman, G.; Wilson, C.; Thurmond, E.; and Schnoll, S. Drug-exposed neonates. *Western Journal of Medicine* 152:559–564, 1990.

Inturrisi, C.E., and Verebey, K. A gas liquid chromatographic method for the quantitative determination of methadone in human plasma and urine. *Journal of Chromatography* 65:361, 1972.

Jeremy, R.J., and Hans, S.L. Behavior of neonates exposed in utero to methadone as assessed on the Brazelton Scale. *Infant Behavior and Development* 8:323–336, 1985.

Kaltenbach, K., and Finnegan, L.P. Perinatal and developmental outcome of infants exposed to methadone in utero. *Neurotoxicology and Teratology* 9:311–313, 1987.

Kaltenbach, K., and Finnegan, L.P. Developmental outcome of infants exposed to methadone in utero: A longitudinal study. *Pediatric Research* 20:57, 1986.

Kaltenbach, K.; Thakur, N.; Weiner, S.; and Finnegan, L.P. The relationship between maternal methadone dose during pregnancy and infant outcome. *Pediatric Research Abstracts*, 1990.

Kaltenbach, K., and Finnegan, L.P. Developmental outcome of children born to methadone maintained women: A review of longitudinal studies. *Neurobehavioral Toxicology and Teratology* 6:271–275, 1984.

Kandall, S.R.; Albin, R.S.; Gartner, L.M.; Lee, K.S.; Eidelman A.; and Lowinson, J. The narcotic dependent mother: Fetal and neonatal consequences. *Early Human Development* 1:159–169, 1977.

Kaplan, S.L.; Kron, R.E.; Phoenix, M.D.; and Finnegan, L.P. Brazelton neonatal assessment at three and twenty-eight days of age: A study of passively addicted infants, high risk infants, and normal infants. In: Alksne, H., and Kauffman, E., eds. *Critical Concerns in the Field of Drug Abuse*. New York: Marcel Dekker, Inc., 1976, pp. 726–730.

Kreek, M.J. Plasma and urine levels of methadone. *New York State Journal of Medicine* 23:2773, 1973.

Kreek, M.J. Opiate ethanol interactions: Implications for biological basis and treatment of combined addictive diseases. In: Harris, L.S. *Problems of Drug Dependence*. National Institute on Drug Abuse Research Monograph 81. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off. 1987.

Kreek, M.J.; Schecter, A.; Gutjahr, C.L.; Bowen, D.; Field, F.; Queenan, J.; and Merkatz, I. Analyses of methadone and other drugs in maternal and neonatal body fluids: Use in evaluation of symptoms in a neonate of mother maintained on methadone. *American Journal of Drug and Alcohol Abuse* 1:409, 1974.

Lifshitz, M.H.; Wilson, G.S.; Smith, E.; and Desmond, M. Fetal and postnatal growth of children born to narcotic-dependent women. *Journal of Pediatrics* 102:686–691, 1983.

Lodge, A. Developmental findings with infants born to mothers on methadone maintenance: A preliminary report. In: Beschner, G., and Rotman, R.B., eds. *Symposium on Comprehensive Health Care for Addicted Families and Their Children*. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1977.

Madden, J.D.; Chappel, J.N.; Zuspan, F.; Gumpel, J.; Meija, A; and Davis, R. Observation and treatment of neonatal narcotic withdrawal. *American Journal of*

Obstetrics and Gynecology 127:199–201, 1977.

Naeye, R.L.; Blane, W.; Coblanc, W.; Leblane, W.; and Khatamee, M.A. Fetal complications of maternal heroin addiction: Abnormal growth, infections, and episodes of stress. *Journal of Pediatrics* 83:1055, 1973.

Novick, D.M., Ochshorn, M.; Ghali, V.; Croxson, T.S.; Mercer, W.D.; Chiorazzi, N.; and Kreek, M.J. Natural killer cell activity and lymphocyte subsets in parenteral heroin abusers and long-term methadone maintenance patients. *Journal of Pharmacology and Experimental Therapeutics* 250:606–610, 1989.

Nelson, L.B.; Ehrlich, S.; Calhoun, J.H.; Matteucci, T.; and Finnegan, L.P. Occurrence of strabismus in infants born to drug dependent women. *American Journal of Diseases of Children* 141:175–178, 1987.

Ostrea, E.M.; Chavez, C.J.; and Strauss, M.E. A study of factors that influence the severity of neonatal narcotic withdrawal. *Journal of Pediatrics* 88:642–645, 1976.

Pasto, M.E.; Ehrlich, S.; Kaltenbach, K.; Graziani, L.; Kurtz, A.; Goldberg, B., and Finnegan, L.P. Cerebral sonographic characteristics and maternal and neonatal risk factors in infants of opiate dependent mothers. In: *Annals of the New York Academy of Science, Proceedings of the Conference on Prenatal Abuse of Licit and Illicit Drugs* 562:355–357, 1989.

Rosen, T.S., and Johnson, H.L. Children of methadone maintained mothers: Follow-up to 18 month of age. *Journal of Pediatrics* 101:192–196, 1982.

Rosen, T.S., and Pippenger, C.E. Disposition of methadone and its relationship to severity of withdrawal in the newborn. *Addictive Diseases* 2:169, 1975.

Silverman, N.S., and Weiner, S.M. Increased HIV testing with an on-site prenatal clinic counselor. Abstract 405, Society of Perinatal Obstetricians Annual Clinical Meeting, 1992. Submitted to *American Journal of Obstetrics and Gynecology.*

Silverman, N.S.; Kim, M.; and Eisen, K. HIV knowledge among substance-addicted pregnant women. *American Journal of Gynecological Health* (in press), 1992.

Stimmel, B.; Goldberg, J.; Reisman, A.; Murphy, R.; and Teets, K. Fetal outcome in narcotic dependent women: The importance of the type of maternal narcotic used. *American Journal of Drug and Alcohol Abuse* 9(4):383–395, 1982–83.

Strauss, M.E.; Lessen-Firestone, J.K.; Starr, R.H.; and Ostrea, E.M. Behavior of narcotic- addicted newborns. *Child Development* 46:887–893, 1975.

Strauss, M.E.; Starr, R.H.; Ostrea, E.M.; Chavez, C.J.; and Stryker, J.C. Behavioral concomitants of prenatal addiction to narcotics. *Journal of Pediatrics.* 89:842–846, 1976.

Sullivan, H.R., and Blake, D.A. Quantitative determination of methadone concentration in human blood, plasma, and urine by gas chromatography. *Research Communications in Chemical Pathology and Pharmacology* 3:467, 1972.

Whittman, B.K., and Segal, S. A comparison of the effects of single- and split-dose methadone administration on the fetus: Ultrasound evaluation. *International Journal of the Addictions* 26(2):213–218, 1991.

Wilson, G.S.; Desmond, M.M.; and Wait, R.B. Follow-up of methadone treated women and their infants: Health developmental and social implications. *Journal of Pediatrics* 98:716–722, 1981.

Wilson, G.S.; McCreary, R.; Kean, J.; and Baxter, C. The development of preschool children of heroin-addicted mothers: A controlled study. *Pediatrics* 63:135–141,1979.

Chapter 10—HIV and Other Infectious Diseases

Susan F. Neshin, M.D.

With the advent of the HIV epidemic and the increase in the incidence of other infectious diseases in the early 1980s, considerations for the medical care of IDUs have undergone major changes in this country. Higher funding levels for drug treatment in the 1960s allowed MMTPs the "luxury" of offering treatment for the primary medical needs of patients. The medical complications of injecting drug use, for example, infectious diseases (e.g., TB and hepatitis B) and infectious and other sequelae (e.g, endocarditis, venous stasis, and kidney and liver disease), seemed manageable using already existing systems of medical care delivery. As funding for drug treatment began to decrease in the 1970s and 1980s, provision of medical services in MMTPs became more "barebones," while the medical needs of IDUs increased.

HIV infection and the increase in rates of other infectious diseases have changed the medical face of injecting drug use. Patients, particularly in high HIV prevalence areas, are sicker and in need of more intensive medical and psychosocial interventions. Many of the previously known sequelae of injecting drug use (TB, hepatitis B) are exacerbated by HIV infection.

To reckon with the problem of HIV infection in IDUs, a two-pronged approach using both prevention and intervention strategies should be used. The AIDS epidemic is first and foremost a public health issue. Drug users and their heterosexual sex partners are the two fastest growing risk groups for AIDS and, therefore, HIV infection. This fact has prompted the U.S. Public Health Service to target centers that treat IDUs, MMTPs in particular, as facilities where ready access to HIV education, counseling, and testing must be made available (Public Health Service Guidelines, 1987).

Counseling and testing those at risk or already infected with HIV are important components of prevention strategies. Counseling and testing are designed to help uninfected individuals initiate and sustain behavioral changes that reduce the risk of infection, to assist infected individuals in taking steps to avoid infecting others, and to aid access to early medical intervention services. Therefore, counseling and testing are essential components of substance abuse treatment in both low and high HIV prevalence areas.

From both the public health and the substance abuse treatment standpoints, methadone maintenance is an excellent treatment modality for chronic IV opiate abusers (Cooper 1989). Numerous studies have demonstrated methadone's unique ability to retain patients (especially new patients) in treatment, as well as to significantly reduce injecting drug use, provided that adequate doses are used and competent ancillary counseling services are offered (Garbutt and Goldstein 1972; Hargreaves 1983; Joe and Simpson 1975; Simpson 1981). Length of time in treatment has consistently been demonstrated to predict treatment outcome (Simpson 1981; Stimmel et al. 1978). In addition, studies have shown that HIV seroprevalence is much lower among patients who have been on long-term methadone maintenance and entered treatment prior to the onset of increasing seroprevalence within the local addict population (Hartel et al. 1988; Novick et al. 1986).

HIV

Implementing HIV Counseling and Testing in MMTPs

The first step in implementing a counseling and testing program is education. All staff should be educated about HIV infection, including risk-reduction guidelines, and the importance and implications of HIV counseling and testing (see attachment 1). In addition, infection control guidelines and the concept of universal precautions should be taught and implemented. In areas of high HIV seroprevalance, an AIDS coordinator can be instrumental as the resident expert and educator, community liaison and educator, and patient resource.

Patients should also be educated about HIV infection—specifically, the modes of transmission (stressing sexual as well as

needle-sharing transmission), assessment of risk status, prevention and risk-reduction guidelines, and the importance of HIV testing in prevention and intervention. This guidance should be given at intake and should be periodically reinforced during treatment by both counseling and medical staff.

HIV counseling and testing should be done by a qualified person who has been trained to do these.[1] Many State health departments as well as the CDC have developed training modules for HIV counseling and testing.[2] (See attachment 2 for a list of State agencies coordinating HIV counseling and testing programs.)

In MMTPs where the majority of patients are IDUs, counseling and testing should be routinely offered, as recommended by the U.S. Public Health Service and many State health departments (Public Health Service Guidelines, 1987). "Routinely offered" is defined as a policy to provide these services to all patients after informing them that the test will be done on-site or through referrals. Pretest counseling should be required for all patients, while HIV testing should be strongly recommended and viewed as a routine clinical procedure for all patients. Individuals have the right to decline to be tested without being denied health care or other services, except where testing is required by law. Counseling and testing should also be made available to needle-sharing and sex partners.

Most States require that patients who agree to counseling and testing sign an informed consent specific to HIV testing. This consent should describe what the HIV antibody test does and does not indicate, test result reporting practices in the program's State, and confidentiality guidelines followed in the program and State (see attachment 3).

Counseling and testing should be provided on-site at the MMTP at no cost to the patient. These services can be provided by an employee of the MMTP or by a representative from an agency that provides counseling and testing. On-site counseling and testing should be confidential, that is, the patient should use his or her own name and identifiers rather than be anonymous. The desired outcome is for patients to discuss their results with those with whom they have developed a therapeutic relationship.

It should be stressed to patients that knowledge of HIV status by specific clinic staff can be integral to providing comprehensive substance abuse treatment. Individual MMTPs should define their criteria for "need to know" in light of the need for confidentiality. In New Jersey, for example, certain substance abuse treatment programs have been funded by the State Department of Health, Division of AIDS Prevention and Control, to be counseling and testing sites. The patient's signed informed consent indicates those staff who "need to know" HIV test results in an emergency situation (see attachment 4). On the other hand, there should be the option of anonymous, off-site HIV counseling and testing if the patient so chooses.

MMTPs are required to adhere to confidentiality guidelines contained in the Federal Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR Part 2). These regulations support the need to establish trusting patient-staff relationships. Assurance of confidentiality in HIV counseling and testing is also imperative if the desired outcome is routine consent to testing. Persons will be more likely to participate in counseling and testing programs if they believe that they will not experience negative consequences in areas such as medical services, housing, employment, and school admission (Public Health Service Guidelines, 1987). Pretest counseling should be given prior to HIV counseling and testing (see attachment 5). Counseling should be done in a manner that makes the person comfortable and assures confidentiality and a non-judgmental attitude. After assessing the person's knowledge of HIV infection and his or her risk of infection, the pretest counseling session should include the following discussion issues:

- Modes of viral transmission
- Prevention measures
- The HIV antibody test and the meaning of both negative and positive results, including the "window period"
- Advantages and disadvantages of testing (see attachment 6)
- The patient's expectation of test results

If the person agrees to be tested, the counselor should assess the patient's existing support system and discuss how the patient might handle negative or positive test results.

All efforts should be made to minimize the waiting period for test results and to bring patients back for the results. All test results should be given in person, not by telephone or mail. Outreach efforts should be made if the patient has already left treatment. If a patient in treatment is not returning for test results, it is important to try to speak to the person and, at minimum, explore reasons for not receiving test results, reiterate prevention guidelines, stress the benefits of early medical intervention, and offer supportive counseling.

Posttest counseling should again be done with assurances of confidentiality. After receiving results, patients should be allowed to absorb the information and vent their feelings. Patients with

negative results should be warned that if they have recently (in the past 3–6 months) engaged in high-risk behaviors, they should be retested 6 months after the most recent possible exposure (see attachment 7). Prevention guidelines should again be stressed.

Patients with positive results may manifest various reactions, for example, anxiety, shock, sadness, guilt, and denial; consultation with a mental health professional should be made available when necessary (see attachment 8). Patients should be advised that a positive test indicates HIV infection, not AIDS. Patients should also be advised of strategies for preventing transmission to others, including information about the possibility of transmission from the woman to the fetus during pregnancy. Referral should be made for medical assessment, which at a minimum should include a physical examination, a baseline T-lymphocyte (CD4) count, a TB screening, and an immunizations update. Depending on what medical services are available in different geographic areas, referrals might be made to private physicians, HIV early intervention treatment programs, hospital-based medical clinics, or community health centers. The benefits of early medical intervention, for example, nutrition, AZT, and PCP prophylaxis, should be stressed. Counselors and patients should discuss the importance of notifying sex and needle-sharing partners, and counselors should offer help in doing so (see attachments 8 and 9).

Reporting HIV and AIDS Information

Programs may be required under State law to report to public health authorities the names of individuals who have been diagnosed with AIDS or are seropositive. Such reports must be made in a manner consistent with the Federal confidentiality regulations regarding drug and alcohol treatment (see appendix D). There are several ways programs can fulfill both requirements.

First, the program can obtain the patient's consent for disclosure of information. Second, disclosures that do not identify an individual as a drug or alcohol patient can be made by programs that are part of a general hospital or larger health care facility. Third, a program can enter into a Qualified Service Organization Agreement with a laboratory or medical care provider that conducts HIV testing or other diagnostic services for the program. Under this agreement, the program gives the names of individuals with reportable conditions to the service provider, which in turn discloses the information without disclosing the person's status as an alcohol or substance abuse patient. Fourth, programs can disclose information under the research exception if the purpose of the State's reporting law is solely to collect research data about the incidence of HIV and AIDS and the State can comply with the research requirements of the law.

Screening for Other Infectious Diseases

This chapter has focused on the importance of providing HIV counseling and testing to all patients in MMTPs. However, this recommendation does not negate the importance of screening for other infectious diseases that are more prevalent in the addicted population than in the general public. FDA/NIDA regulations already mandate tuberculin skin testing (21 CFR §291.505(d)(3)(i)), and the ADAMHA Reorganization Act of 1992 (P.L. 102-321) requires subrecipients of Substance Abuse Prevention and Treatment Block Grant funds to make TB counseling, screening, and treatment[3] available to patients, as a condition of receiving those funds. Federal regulations also mandate a serologic test for syphilis for all patients on admission to an MMTP (21 CFR §291.505(d)(3)(i)). Screening for other infectious diseases, including viral hepatitides and STDs, will also be reviewed. While screening is important and the concept of "one-stop shopping" might recommend on-site screening and followup evaluation and treatment, these are often not logistically or financially feasible in an MMTP. Where only minimal medical or public health services are available on-site, it is crucial that linkages are made with medical and public health services in the community to effect the necessary medical screening and followup.

Tuberculosis

TB cases in the United States have been on the rise since 1986, and evidence suggests that to a large extent this phenomenon is due to reactivation of latent infections in individuals also infected with HIV. IDUs are a high-risk group for TB as well as HIV infection. Because tuberculous exposure can be treated with prophylaxis to limit progression to active TB, and because TB can be treated to prevent further morbidity and mortality as well as prevent airborne transmission of the tubercle bacillus, testing of IDUs for both TB and HIV infection is important.

Patients in MMTPs should receive a Purified Protein Derivative (PPD) skin test for TB both on admission and annually, unless they are known to be PPD positive. Specifically, the Mantoux test should be used, which requires injecting five tuberculin units of PPD intradermally. A test is considered positive if there is 10 mm or more induration in a person who is known to be HIV negative. Those who are HIV seropositive or

who are at high risk for HIV infection (i.e., most of the methadone maintenance population) are considered PPD positive if there is a 5mm induration or more.

All patients with a positive PPD should receive a chest x-ray. The medical staff of the MMTP should facilitate the referral for the patient to be evaluated at the appropriate facility (e.g., county TB clinic, affiliated or local hospital clinic, patient's private physician, etc.) and provide the necessary followup. If the patient is placed on isoniazid (INH) prophylaxis, the MMTP can be involved in treatment compliance by monitoring daily INH intake.

A negative PPD skin test means the patient has no tuberculous exposure or infection, is in the incubation period of infection, or has an inability to respond to the skin test (i.e., is anergic). Immunocompromised HIV-infected patients are frequently anergic. Anergy testing can be a useful tool to screen out true from false PPD negative tests. The merits and disadvantages of anergy testing have been reviewed by the CDC (CDC 1991).

In addition to PPD skin testing, it is important to look for and question patients for the presence of the following symptoms of active TB: Cough, fever, night sweats, weight loss, and fatigue. As noted earlier, programs receiving substance abuse block grant funds must make treatment available to those patients identified with active TB by symptoms or a chest x-ray or both.

The MMTP can also be involved in monitoring medication compliance, as medication regimens require multiple drugs. Compliance with medication regimens for the duration of recommended treatment is important in preventing the emergence of multi-drug-resistant TB, the incidence of which has been on the rise. When rifampin is used, the methadone dose often needs to be increased or split or both (BID dosing) because of rifampin's acceleration of the clearance of drugs metabolized in the liver.

New staff in MMTPs should also be screened for TB, and all staff should be tested for TB at regular intervals depending on local TB prevalence.

Hepatitis B

HBV infection is common among IDUs. Between 60 and 80 percent of IDUs have evidence of prior HBV infection. The HBV chronic carrier (defined as a person who is serum hepatitis B surface antigen (HBsAG) positive for 6 months or more) is an important vector in the transmission of HBV infection. A vaccine for hepatitis B has been available since 1982, yet the incidence of this disease has continued to rise, primarily because of injecting drug use. Screening for HBV is important to identify acute cases of HBV infection, chronic carrier states, untreated symptomatic chronic active hepatitis, and those who are not protected against HBV infection and can therefore benefit from vaccination.

On admission to an MMTP, all patients should ideally be screened with both the anti-hepatitis B core antibody and hepatitis B surface antigen blood tests. If the patient is surface-antigen positive, further medical evaluation and counseling about avoiding transmission to sex and needle-sharing partners are important. Medical evaluation, including other liver function testing, can be done in-house or by referral.

If core-antibody and surface-antigen negative, the patient should be advised of his or her susceptibility to HBV infection and the value of vaccination. Vaccination should be offered to patients. The decision as to where this will be done and who will pay for the vaccine depends on local conditions.

All staff in an MMTP who are considered at risk for exposure to HBV must be given hepatitis B vaccine according to OSHA standards for bloodborne pathogens (29 CFR §1910.1200).

Hepatitis A, C, and D

Routine screening for hepatitis A, C, and D in MMTPs is not recommended at this time, although all these types of viral hepatitides are associated with injecting drug use.

With the advent of both crack cocaine and HIV infection, STDs have been on the rise. In general, all infectious diseases have potential for a more florid and/or prolonged presentation in immuno-compromised individuals. Therefore, early recognition and aggressive therapy are crucial for adequate treatment.

Syphilis

All patients should be screened at intake with a serologic blood test for syphilis, such as the Rapid Plasma Reagent (RPR) or the Venereal Disease Reference Laboratory (VDRL). All positive tests should be confirmed with a treponemal antigen test, such as the Fluorescent Treponemal Antibody Absorption Test, as false-positive results to nontreponemal serologic tests (RPR, VDRL) are common in IDUs. All those with a confirmed positive serologic test for syphilis should be treated. Treatment may be done in-house or by referral to a local STD clinic, hospital, or physician's office.

Gonorrhea and Chlamydia

Ideally, all patients entering an MMTP should be screened for gonorrhea and chlamydia, especially if they have a history of STDs. Chlamydia, which is often seen as a comorbid condition with gonorrhea, is now the most

common sexually transmitted disease in the United States. Both screening tests require intraurethral (male) or endocervical (female) smears to be done; obviously, a pelvic exam of women is also required.

Herpes and Venereal Warts

Herpes and venereal warts are other STDs to look for. These viral infections manifest more severely in immunocompromised and therefore HIV-positive patients.

General Issues

As discussed above with respect to HIV counseling and testing, programs need to comply with confidentiality regulations (42 CFR Part 2). Program staffs should develop their own protocols and policies in compliance with Federal and State laws.

When involved in screening for most of the infectious diseases discussed, programs need to provide or make direct referrals for education and counseling, contact tracing, and partner notification.

Recommendations

- Educate all staff about HIV infection, including risk-reduction guidelines, the importance and implications of HIV counseling and testing, and infection control guidelines.
- Provide all patients entering an MMTP with HIV education, including information on modes of transmission, assessment of risk status, prevention and risk-reduction guidelines, and the importance of HIV counseling and testing in prevention and intervention.
- Routinely offer HIV counseling and testing (both on-site and off-site by referral) to all patients in MMTPs and their sex and needle-sharing partners.
- Obtain informed consent from patients for HIV counseling and testing prior to testing. Adhere strictly to Federal confidentiality guidelines.
- Train counseling and testing personnel to do pretest and posttest counseling.
- Have mental health professionals readily available to manage patients' potential negative reactions to HIV test results.
- Ensure that at least one identified staff person is familiar with medical and public health services that provide HIV assessment, early intervention, and treatment in the patients' geographic area, and refer patients appropriately.
- Encourage patients who are HIV positive to notify their sex and needle-sharing partners of their positive status. In some States, there may be a legal mandate for HIV-positive persons to do so.
- Provide TB counseling, screening, and treatment.
- Screen new MMTP staff for TB, and test all staff for TB annually.
- Provide screening for viral hepatitides and STDs, and ensure that any necessary medical followup occurs either on-site or through referral to community medical services.
- Provide hepatitis B vaccine to all staff considered to be at risk for exposure to HBV.

References

Centers for Disease Control. Sexually transmitted diseases: Treatment guidelines. *Morbidity and Mortality Weekly Report* 38(September 1):S–8, 1989.

Centers for Disease Control. Purified protein derivative—Tuberculin anergy and HIV infection: Guidelines for anergy testing and management of anergic persons at risk of tuberculosis. *Mortality and Morbidity Weekly Report* 40(April 26):RR-5, 1991. pp. 27–33.

Cooper, J.R. Methadone treatment and acquired immunodeficiency syndrome. *Journal of the American Medical Association* 262:1664–1668, 1989.

Garbutt, G.D., and Goldstein, A. Blind comparison of three methadone maintenance dosages in 180 patients. In: *Proceedings of the Fourth National Conference on Methadone Treatment*. New York, NY: National Association for Prevention of Addiction to Narcotics, 1972.

Hargreaves, W.A. Methadone dose and duration for maintenance treatment. In: Cooper, J.R.; Altman, F.; Brown, B.S.; and Czechowicz, D., eds. *Research on the Treatment of Narcotic Addiction: State of the Art.* Rockville, MD: National Institute on Drug Abuse, 1983.

Hartel, D.; Selwyn, P.A.; Schoenbaum, E.E.; Klein, R.S.; and Friedland, G.H. Methadone maintenance treatment and reduced risk of AIDS and AIDS-specific mortality in intravenous drug users. Paper presented at the Fourth International Conference on AIDS, June 1988, Stockholm, Sweden.

Joe, G.W., and Simpson, D.D. Retention in treatment of drug abusers: 1971–1972 DARP admission. *American Journal of Drug and Alcohol Abuse* 2:63–71, 1975.

Novick, D.M.; Khan, I.; and Kreek, M.J. Acquired immunodeficiency syndrome and infection with hepatitis viruses in individuals abusing drugs by injection. *Bulletin of Narcotics* 38:15–25, 1986.

Public Health Service guidelines for counseling and antibody testing to prevent HIV infection and AIDS. *Morbidity and Mortality*

Weekly Report 36(August 14):509–514, 1987.

Simpson, D.D. The relation of time spent in drug abuse treatment to post-treatment outcome. *American Journal of Psychiatry* 136:1449–1453, 1979.

Simpson, D.D. Treatment for drug abuse: Follow up outcomes and length of time spent. *Archives of General Psychiatry* 38:875–880, 1981.

Simpson, D.D.; Savage, L.V.; and Lloyd, M.R. Follow up evaluation of drug abuse during 1969 to 1972. *Archives of General Psychiatry* 36:772–780, 1979.

Stimmel, B.; Goldberg, J.; Cohen, M.; and Rotkopf, E. Detoxification from methadone maintenance: Risk factors associated with relapse to narcotic use. *Annals of the New York Academy of Sciences* 311:173–180, 1978.

Endnotes

1. Some States may require certification to provide this service.

2. For more information, call the CDC, Division of Sexually Transmitted Diseases, HIV Prevention, Training and Education Branch, at (404) 639-1233.

3. Funding for these activities can come from the block grant or any other Federal, State, or local funding source.

POLICY AND PROCEDURE FOR HIV COUNSELING, TESTING, AND REFERRAL IN DRUG TREATMENT PROGRAMS

I. Background

Until recently, little could be done to prevent the progression of infection with human immunodeficiency virus (HIV). The outcome was usually fatal, most often as a consequence of opportunistic infections.

This situation has dramatically changed. Early medical intervention can now produce significant benefits. Some of the severe infections that led to death in the past can be delayed, if not prevented. Antiviral chemotherapy, directed against HIV, can delay progressive immunodeficiency and neurologic disease.

So long as little could be done to forestall the ravages of HIV infection, many argued that little was to be gained by serologic testing to identify asymptomatic HIV infection. Now that early intervention can produce important benefits, a major effort must be made to identify infected persons and to encourage them to enter a program of effective medical management. (*Identification and Management of Asymptomatic HIV-Infected Persons in New Jersey Academy of Medicine and the New Jersey State Department of Health*).

II. Policy

Every person who has had potential exposure to HIV between 1976 and the present should be strongly encouraged to be tested. Such individuals include:

1. Men who have had active or passive oral and anal sexual intercourse with other men.

2. People who have shared needles or other materials related to injection of drugs (syringes or other "works") that might have been contaminated with blood.

3. People who have sexual intercourse (vaginal, oral, or anal) with individuals known or suspected of having AIDS or being infected with HIV.

4. People who have engaged in sex for drugs or money.

5. People who have had, or may have had, sexual intercourse with individuals in any of the above categories.

6. People who received blood or blood products (not including immune serum globulin or albumin) between 1978 and mid-1985, particularly those who receive multiple units of blood or blood products, or products containing pooled blood from multiple donors.

Several diseases are strongly associated with HIV infection, so the diagnosis of any of the following conditions also indicates the need for HIV testing:

7. Tuberculosis.

8. Any sexually transmitted disease acquired between 1975 and the present.

9. Hepatitis B or non-A, non-B hepatitis (NANS hepatitis).

10. Any illness consistent with clinical AIDS or an AIDS-related condition.

Epidemiologic data indicated that individuals in the following settings should also be tested:

11. Every pregnant woman, because of demonstrated risk of transmission of HIV to newborns.

    Women in the childbearing years who plan to become pregnant are also candidates for testing, since detection of infection can allow the use of techniques to prevent pregnancy.

12. All donors of blood, organs, or sperm, as condition of donation.

Testing should also be encouraged if there is any question as to whether an individual falls into one of these categories. In addition, any person who is concerned about possible exposure to HIV or the possibility of HIV disease should be tested. (*Identification and Management of Asymptomatic HIV-Infected Persons in New Jersey Academy of Medicine and the New Jersey State Department of Health*).

Clearly, a large number of patients in drug treatment centers fall into one or more of the above categories. The NJ Department of Health is therefore requiring the active participation of all state funded drug treatment programs in encouraging HIV counseling and testing of at-risk program patients and subsequent referrals for assessment and appropriate treatment for those found to be positive. Referrals should be made first to private physicians, to local clinics, and lastly to an early intervention center if the client is a resident of that catchment area.

III. HIV Counseling and Testing Procedures

The NJ Division of AIDS has made HIV counseling and testing available to all drug treatment programs in one of three ways:

1. Direct contract with treatment agency to hire program employees to provide counseling and testing on site.

2. On-site counseling and testing by Counseling and Testing Sites (CTS) personnel.

3. Testing off-site by referral to a CTS.

All Counseling and Testing Sites (CTS) personnel are required to successfully complete a Division of AIDS training course, such as the 5-day HIV Counselor Training Program. All patients entering drug treatment programs are to receive education about AIDS and pretest counseling as part of the program's standard of care. Those "at risk" are to be encouraged to be tested, as part of intake procedure, through the available mechanism as above. All patients, whether or not there is a history of intravenous drug use, should be encouraged to be tested. All patients are required to consent to testing in writing. They may not be required to be tested, nor may testing be a prerequisite for admission to drug treatment. A consent form for testing at drug and alcohol treatment programs has been developed that explains that HIV test results and records will be available only to personnel who have a "need to know." This is defined as "physician, nursing staff, designated Treatment Assessment Program (TAP) liaison, AIDS coordinator, and counseling and testing staff." This form must be signed by all patients tested on site at the Drug Treatment Center (DTC). (The medical director may determine who has a "need to know" in an emergency.) Patients who will not consent to this will be referred to CTS. All patients known to be drug program clients will be encouraged to sign a record release to their DTC if they are tested at a testing center; however, here it will not be required. HIV information received from a CTS shall be available *only* to the personnel with a "need to know" as listed above. In programs that have *none* of the listed positions on site, the program director is considered the only person with a "need to know."

All patients found to be infected with HIV will be informed of the nearest TAP or similar resource for assessment and prophylaxis (if indicated) by the person who is interpreting the test results to the patient. This person will also refer all HIV-infected patients to the Division of AIDS - Notification Assistance Program (NAP) so that sexual and/or needle-sharing contacts may be notified. In programs with an AIDS coordinator and/or TAP liaison, referrals should be coordinated and appropriate records kept. **As always**, information provided to personnel other than those listed as "need to know" requires the standard record release for substance abuse programs, whether in or out of the DTC.

Within 60 days of admission, **every** patient remaining in the program is to be contacted by a "need to know" staff person to encourage testing if the patient was not tested on admission; receipt of results if the patient did not receive his/her results; and compliance with assessment and prophylaxis. (Only staff certified through the Division of AIDS Counselor Training Program may give test results, except that this does not apply to physicians.) This contact must be documented.

IV. Records

A separate HIV file is to be established for every patient tested or for whom results are received from any source. This file is to be locked and placed in a secure area accessible only to those listed as "need to know." HIV test results and documentation are to be placed in this file regardless of whether the test is negative or positive. If the patient has not returned for post-test counseling and results, this is to be documented so that it can be picked up at the 60-day contact. **All** HIV documents related to individual patients are to be kept in this file and may not be left in offices, etc.

V. Conclusion

Drug treatment program staff listed as "need to know" bear a special responsibility to be aware of the psychosocial impact of HIV testing and followup, to remain sensitive to the clients' needs and emotional status, and to make appropriate referrals to mental health personnel. Releases to provide information must meet existing State and Federal guidelines and specify HIV-related content. A release for "medical records" is insufficient, for example.

Patients, of course, may be encouraged to discuss their HIV status with their primary counselor and/or at appropriate group or individual counseling sessions, and will generally do so when comfortable. They *may not* be required to do so. Such patient confidences may be discussed only with staff listed as having a "need to know." An individual's HIV status should not be part of the social chart.

STATE HIV COUNSELING AND TESTING PROGRAMS

Office of Epidemiology
Department of Health and Social Services
3601 C Street, Suite 540
Anchorage, AK 99524-0249
Phone: (907) 561-4406
Fax: (907) 562-7802

Division of STD Control
Department of Public Health
434 Monroe Street, Room 669
Montgomery, AL 36130-1701
Phone: (205) 242-5017,8-534-7260
Fax: (205) 240-3097

Bureau of Disease Control & Rehabilitation Services
434 Monroe Street, Room 766
Montgomery, AL 36130-1701
Phone: (205) 242-5838
Fax: (205) 240-30978

Division of AIDS/STD
Department of Health
4815 West Markham, Room 455
Room 455, Slot 33
Little Rock, AR 7205-3867
Phone: (501) 661-2133
Fax: (501) 661-2468

AIDS Program Coordinator
Department of Health
Pago Pago, AS 96799
Phone: 9-011-(684) 633-4071
Fax: 9-011-(684) 633-1869

Department of Health Services
Division of Disease Prevention
3008 North 3rd Street
Phoenix, AZ 85012
Phone: (602) 250-5842 or 5819
Fax: (602) 230-5817

Department of Health Services
Division of Disease Prevention
600 South Commonwealth Avenue
6th Floor
Los Angeles, CA 90005

Office of AIDS
Department of Health Services
P.O. Box 942732
Sacramento, CA 94234-7320
Phone: (916) 323-7415
Fax: (916) 323-4642

AIDS Activity Office
Department of Public Health
25 Van Ness Avenue
San Francisco, CA 94102
Phone: (415) 554-9040
Fax: (415) 431-7547

STD/AIDS Section
Department of Health
4210 East 11th Avenue
Denver, CO 80220
Phone: (303) 331-8320
Fax: (303) 377-0915

HIV Operations Coordinator
Department of Health Services
150 Washington Street
Hartford, CT 06106
Phone: (203) 566-2048
Fax: (203) 566-2923

Bureau of Disease Prevention
Division of Public Health
P.O. Box 637
Dover, DE 19903
Phone: (302) 739-3032
Fax: (302) 739-6617

Office of AIDS Activities
Commission of Public Health
1660 L Street, N.W., 7th Floor
Washington, DC 20036
Phone: (202) 673-3425
Fax: (202) 724-3795

AIDS Program
Department of Health
Rehabilitative Services
1309 Winewood Boulevard, Building 2

FSM National Government
Department of Human Resources
P.O. Box PS 70
Kolonia, Pohnpei FM 96941
Phone: 9-011-(691) 320-2619
Fax: 9-011- (691) 320-5263

Office of Infectious Diseases
Department of Human Resources
878 Peachtree Street, NE
Atlanta, GA 30309
Phone: (404) 894-5122
Fax: (404) 894-7799

AIDS Program Coordinator
Department of Public Health & Social Services
Government of Guam
P.O. Box 2816
Agana, GU 96910
Phone: 9-011-(671) 734-7142
Fax: 9-011-(671) 734-5910

STD/HIV Prevention Program
Department of Health
3627 Kilauea Avenue, Room 304
Honolulu, HI 96816-2399
Phone: (808) 735-5304
8-551-2664
Fax: (808) 735-5318

Division of Health Protection
Department of Public Health
Lucas State Office Building
Des Moines, IA 50319-0075
Phone: (515) 281-4938
Fax: (515) 242-6284

STD/HIV Supervisor
Bureau of Communicable Disease Prevention
Department of Health and Welfare
450 West State Street
Boise, ID 83720
Phone: (208) 334-6526
Fax: (208) 334-6581

Office of AIDS Prevention
Department of Health
50 West Washington Street
Room 233-South
Chicago, IL 60602
Phone: (312) 744-4312
Fax: (312) 236-5411

AIDS Activity Section
111 North Canal Street
Suite 135
Chicago, IL 60601
Phone: (312) 814-4846
Fax: (312) 814-4844

AIDS Program
State Board of Health
1330 West Michigan Street
P.O. Box 1964
Indianapolis, IN 46206-1964
Phone: (317) 633-0851
Fax: (317) 633-0776

Bureau of Disease Control
Department of Health & Environment
109 SW. 9th Street
Mills Building
Topeka, KS 66612-1271
Phone: (913) 296-0022
Fax: (913) 296-4197

Health Promotion
Cabinet for Human Resources
275 East Main Street
Frankfort, KY 40621
Phone: (502) 564-7112
Fax: (502) 564-6533

HIV/AIDS Services (HAS)
Office of Public Health
Department of Health and Hospitals
325 Loyola Avenue, Room 618
New Orleans, LA 70112
Phone: (504) 568-5508
Fax: (504) 568-5507

AIDS Bureau
Department of Public Health
150 Tremont Street, 11th Floor
Boston, MA 02111
Phone: (617) 727-0368
Fax: (617) 727-6943

Center for AIDS Education
Department of Health & Mental Hygiene
201 West Preston Street
Baltimore, MD 21201
Phone: (410) 225-5019
Fax: (410) 333-5954

AIDS/HIV Program, Bureau of Health
Department of Human Services
State House - Station 11
Department of Human Services
157 Capitol Street
Augusta, ME 04333-0011
Phone: (207) 289-3591
Fax: (207) 289-4172

Secretary of Health
Ministry of Health Services
Republic of the Marshall Islands
P.O. Box 16
Majuro, MH 96960
Phone: 9-011-(692) 625-3355
Fax: 9-011-(692) 625-3432

AIDS Prevention Project
Division of Disease Control
Bureau of Infectious Disease Control
P.O. Box 30195
Lansing, MI 48909
Phone: (517) 335-8468
Fax: (517) 335-8395

Health Program Manager
AIDS/STD Prevention Services Section
State Department of Health
717 Delaware Street, SE
Minneapolis, MN 55440
Phone: (612) 623-5698
Fax: (612) 623-5743

AIDS Program
Department of Health
P.O. Box 570
Jefferson City, MO 65102-0570
Phone: (314) 751-6149
Fax: (314) 751-6010

Department of Public Health
& Environmental Services
Commonwealth Health Center
P.O. Box 409 CK
Saipan, MP 96950
Phone: 9-011(670) 234-8950

AIDS Program Director
Department of Public Health
P.O. Box 1700
Jackson, MS 39215-1700
Phone: (601) 960-7725
Fax: (601) 960-7948

AIDS/STD Program
Department of Health &
Environmental Science
Cogswell Building
Helena, MT 59620
Phone: (406) 444-2457
Fax: (406) 444-2606

Communicable Disease Control
AIDS Program
Department of Environment, Health,
& Natural Resources
P.O. Box 27687
Raleigh, NC 27611-7687
Phone: (919) 733-7301
Fax: (919) 733-1020

AIDS Program Director
Division of Disease Control
Department of Health &
Consolidated Laboratories
State Capitol Building
Bismarck, ND 58505-0200
Phone: (701) 224-2378
Fax: (701) 224-3000

AIDS Program
Department of Health
P.O. Box 95007
Lincoln, NE 68509-5007
Phone: (402) 471-2937
Fax: (402) 471-0383

HIV/AIDS Program
Bureau of Disease Control
Division of Public Health Services
6 Hazen Drive
Concord, NH 03301
Phone: (603) 271-4480
Fax: (603) 271-3745

Division of AIDS Prevention & Control
State Department of Health
363 West State Street
Tenton, NJ 08625
Phone: (609) 984-5874
Fax: (609) 292-3580

AIDS Prevention Program
Health Department
1190 St. Francis Drive
Harold Runnels Building
Santa Fe, NM 87503
Phone: (505) 827-0086
Fax: (505) 827-0097

STD/AIDS Division
Department of Human Resources
505 East King Street, Room 200
Carson City, NV 89710
Phone: (702) 687-4804
Fax: (702) 687-4988

AIDS Institute
Department of Health
Room 503, Tower, ESP
Albany, NY 12237
Phone: (518) 473-7238
Fax: (518) 473-7286

AIDS Program Services Intervention
NYC Department of Health
125 Worth Street
New York, NY 10013
Phone: (212) 566-7103
Fax: (212) 566-5970

AIDS Activities Unit
Department of Health
246 North High Street, 8th Floor
P.O. Box 118
Columbus, OH 43266-0118
Phone: (614) 466-0295
Fax: (614) 644-1909

STD/HIV Program
Epidemiology Service
Department of Health
P.O. Box 53551
Oklahoma City, OK 73152
Phone: (405) 271-4061
Fax: (405) 271-5149

Oregon HIV Program Manager
State Department of Health
800 NE. Oregon St., #21, Suite 745
Portland, OR 97232
Phone: (503) 731-4029
Fax: (503) 731-4082

Bureau of HIV/AIDS
State Department of Health
P.O. Box 90
Harrisburg, PA 17108
Phone: (717) 783-0479
Fax: (717) 783-3794

AIDS Activities Coordinating Office
1220 Sansom Street, 7th Floor
Philadelphia, PA 19107
Phone: (215) 686-1807
Fax: (215) 238-0842

AIDS Central Office (OCAS)
Department of Health
Gonzalez Padin Building, 6th Floor
P.O. Box 71423
San Juan, PR 00936-1423
Phone: (809) 721-2000
Fax: (809) 723-3565

AIDS Project Coordinator
Bureau of Health Services
Republic of Palau
P.O. Box 100
Koror, Palau PW 96940
Phone: 9-011-(680) 488-2813

Division of Disease Control
Department of Health
3 Capital Hill - Room 105
Providence, RI 02908-5097
Phone: (401) 277-2320
Fax: (401) 277-1272

AIDS Division
Department of Health & Environmental Control
2600 Bull Street
Columbia, SC 29201
Phone: (803) 737-4110
Fax: (803) 737-3979

AIDS Coordinator
Division of Public Health
Department of Health
523 East Capitol
Pierre, SD 57501-3182
Phone: (605) 773-3364
Fax: (605) 773-5904

AIDS Program
Department of Health & Environment
C2-221 Cordell Hull Building
Nashville, TN 37247-4947
Phone: (615) 741-7500
Fax: (615) 741-2491

HIV Division
Department of Health
110 West 49th Street
Austin, TX 78756-3199
Phone: (512) 458-7209
Fax: (512) 458-7407

Bureau of STD/HIV Prevention
City of Houston
8000 North Stadium Drive
Houston, TX 77054
Phone: (713) 794-9164
Fax: (713) 794-9464

Division of Community Health Services
Bureau of HIV/AIDS Prevention & Control
288 North 1460 West
P.O. Box 16700
Salt Lake, UT 84116-0700
Phone: (801) 538-6096
Fax: (801) 538-6036

Bureau of STD/AIDS Control
Department of Health
P.O. Box 2448, Room 112
Richmond, VA 23218
Phone: (804) 786-6267
8-936-6267
Fax: (804) 786-7528

Department of Health
516 Strand Street
Frederiksted, St. Croix, VI 00840
Phone: (809) 772-5895
Fax: (809) 772-5895

STD Control Section
Department of Health
60 Main Street
P.O. Box 70
Burlington, VT 05402
Phone: (802) 863-7245
Fax: (802) 863-7425

Department of Health
HIV/AIDS Prevention, LJ-17
P.O. Box 47840
Olympia, WA 98504-7840
Phone: (206) 586-0427
Fax: (206) 321-5525

AIDS/HIV Program
Division of Health
P.O. Box 309
Madison, WI 53701-0309
Phone: (608) 266-9853
Fax: (608) 267-3696

STD/HIV Control Program
Department of Health &
Human Resources
1422 Washington Street, East
Charleston, WV 25301
Phone: (304) 348-2950
Fax: (304) 348-6335

AIDS Prevention Program
Division of Preventive Medicine
Hathaway Building, 4th Floor
Cheyenne, WY 82002
Phone: (307) 777-5932
Fax: (307) 777-5402

SAMPLE CONSENT FORM FOR HIV ANTIBODY TESTING

The human immunodeficiency virus (HIV) has been recognized by most experts to be closely associated with acquired immunodeficiency syndrome (AIDS).

Tests are now available to determine the presence of antibodies to HIV in the blood. Antibodies are substances made by the body to fight infection. After the virus enters the body, it takes time to produce antibodies. A person may be infected with the virus, but more time may be needed for the body to make antibodies. For this reason, the antibody test result may show that a person is "negative" (does not have antibody), but the person may actually carry the virus in his or her body or body fluids.

A positive HIV antibody test indicates the present of antibodies produced by the body as a result of invasion by the human immunodeficiency virus. HIV infection is a chronic and progressive illness. However, a positive antibody test does not mean a person has AIDS nor will necessarily come down with AIDS.

If your HIV antibody test results are known, and are positive, your doctor may be able to prescribe medications that can prevent or delay you from getting symptoms of progressive HIV illness. Also, the test may help your doctor decide how best to treat you with vaccines and for some other illnesses or exposures, such as tuberculosis. It may help you to make personal decisions if you know you're at risk for getting the virus or giving it to some else.

If your blood test is positive and the test result is known by others, they may think you have AIDS. This may not be true but you might be discriminated against by friends, family, employers, landlords, insurance companies, and others. Therefore, you should be extremely careful in disclosing your test results. The New York State Division of Human Rights and the New York City Commission on Human Rights will investigate and prosecute instances of illegal discrimination against HIV-infected persons.

New York State has laws and regulations that protect the confidentiality of medical records and laboratory test results. Nevertheless, as with any sensitive information, there is the potential for unauthorized disclosure or release of the information. Should this occur, contact the Department of Health for assistance.

I have read (or have had read to me) the above description of the HIV-antibody test and understand the limitations and possible consequences of this test. I have also had explained to me the blood-drawing procedures and the risks, if any.

I agree to testing for HIV antibodies.

_____ Date _____

Signature of Patient or Person Legally Authorized to Consent on Patient's Behalf (State relationship)

Consent form recommended by the New York State Department of Health with changes by the American Society of Addiction Medicine (1991). A Spanish translation of the original form is available as a sample from the Department of Health. This consent form is provided as a sample, and may not be appropriate in all situations.

Reprinted from the American Society of Addiction Medicine's Guidelines for Facilities Treating Chemically Dependent Patients at Risk for AIDS or Infected by HIV. pp. 23-24, revised April 1991.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ANTIBODY TEST
DRUG AND ALCOHOL TREATMENT CLINICS
CONSENT FORM

This is not a test for AIDS. This is a test for antibodies to the virus called HIV. A counselor has given and read to me a copy of the fact sheet about the test. She/he has told me what a negative or positive test result means. On my return visit, a counselor will explain my test results to me.

I understand that knowing my HIV result is important to my health. I understand that I will be tested confidentially at this clinic. Confidential testing means that I will sign my name, and fill in my address and phone number on this form. This is the same basic information I would provide if tested at any clinic, hospital, or private physician. This is the best way for me to enter into treatment and learn of other available services. It is also a way for someone to reach me if I cannot return for my test results.

I will get a code number. This number will be on the consent form, lab slip and blood tube. The lab slip and blood tube will be sent to the State Health Department where the test will be done. My code number, not my name, will be on the lab slip and the blood tube.

All records are kept under lock and key, and only my health care providers at this drug/alcohol clinic (physician, nursing staff, designated Treatment Assessment Program (TAP) liaison, AIDS coordinator, and counseling and testing staff) will have access to this information. In an emergency situation, the medical director of the clinic will determine who has a need to know.

This information is confidential and cannot be released to those not involved in my treatment without my written consent or a court order.

My results and other information about me will only be sent to other agencies if I sign a release form. I have read or someone has read this form to me. All of my questions have been answered.

(Signature of Witness)	(Signature of Client)
(Code Number)	(Street Address)
(Date)	(City and State)
(Name of D/A Treatment Clinic)	(Phone Number)

GUIDELINES FOR PRETEST COUNSELING

I. Introduction

- Introduce yourself.
- State purpose of the session.
- Make client feel comfortable about the session and discuss any related concerns.
- Explain that anything discussed in the session will be strictly confidential and that you will be completely nonjudgmental.

II. Risk Assessment

- Explain purpose of clinic record.
- Complete clinic record questionnaire.

III. Assess Client's Knowledge of HIV Infection

- Allow client to explain his or her knowledge of the various stages of HIV infection (i.e., asymptomatic, ARC, AIDS).
- Clarify any misconceptions that client may have relayed to you.
- Explain modes of transmission and modes of nontransmission.
- Discuss prevention measures and barriers to their implementation.
- Review client's risk of infection.

IV. Explain the HIV Antibody Test

- Explain that it is not a test to detect AIDS, but rather, antibodies to the virus that can cause AIDS.
- Discuss the meaning of a negative test.
- Discuss the meaning of a positive test.
- Explain ELISA and Western blot.
- Discuss and define incubation period for client; distinguish between appearance of symptoms and appearance of antibodies.
- Discuss confidentiality of records.

V. Testing

- Help client make decision about testing.
- Obtain signed informed consent.
- Elicit from client possible reactions to test results.
- Assess client's support system.
- Discuss how the client will deal with 3-week waiting period.
- Have client formulate a workable plan for prevention and risk reduction.
- Summarize, give handout materials, and leave the door open for client to return for future counseling and/or testing.
- Prepare for venipuncture by completing lab slip.
- Give appointment card to client to call for result.
- Inform client that a return visit is necessary to obtain test result.

HIV TESTING: AN INDIVIDUAL DECISION

Testing for HIV antibody involves benefits and risks. It requires careful thought. Following are some of the advantages and disadvantages of testing, as compiled by members of the American Society of Addiction Medicine's AIDS and Chemical Dependency Committee.

ADVANTAGES

(1) MEDICAL-To guide therapeutic interventions

(a) DIAGNOSIS SIGNIFICANCE-HIV testing has diagnostic significance in a patient at risk in the differential diagnosis of unusual illnesses.

(b) TREATMENT-Infections may be approached differently in a HIV-positive patient. TB, pneumonia, hepatitis B, delta infection, bacterial endocarditis, sexually transmitted diseases, and risk of gynecologic cancers may require closer observation and more aggressive treatment in an HIV positive patient.

(c) INTERVENTION

1. Rigorous assessment and early intervention may prevent or improve the prognosis for many HIV-related conditions.
2. Treatments are available which may prevent or delay seropositive individuals from developing progressive HIV illness.
3. Knowledge of HIV status may enable access to current research protocols.
4. Immunosuppressive therapy for another disease may not be indicated for an HIV-positive patient.

(d) PREVENTION

1. Knowledge of HIV status enables better-informed health decisions regarding pregnancy.
2. If a vaccine become available, it may be offered to uninfected persons to prevent them from becoming infected with the virus.

(2) PSYCHOLOGICAL

(a) An HIV negative result may relieve anxiety.

(b) An HIV positive result may encourage changes to make remaining life more meaningful.

DISADVANTAGES

(1) CHEMICAL DEPENDENCY

(a) Knowledge of positive test may induce relapse or termination of treatment.

(2) SOCIAL

(a) Ostracism from family, friends, and society is possible. HIV positive persons lack support of others when they most need it. Lack of confidentiality and anti-discrimination policies intensify that risk.

(3) PSYCHOLOGICAL

(a) Potential for depression, stress, anxiety, and suicide exists.

(b) Reactions to results may be erratic, even dangerous. A positive test may result in pessimism, hopelessness, and self-destructive behaviors, including drug or alcohol abuse or unsafe sex practices.

(4) ECONOMIC

(a) Potential for job loss and disqualification for health and life insurance is highly likely. Again, lack of confidentiality and anti-discrimination policies intensify this risk.

(5) PUBLIC HEALTH

(a) A negative test may discourage modification of risk behavior. A positive test may encourage vindictive or retaliatory behavior leading to further infection.

Reprinted from The American Society of Addiction Medicine's *Guidelines for Facilities Treating Chemically Dependent Patients At Risk for AIDS or Infected by HIV Virus*, P. 25-26, revised June 1988.

GUIDELINES FOR POSTTEST COUNSELING
NEGATIVE RESULTS

I. Introduction

-Review client's clinic record before the session begins

-Introduce or reintroduce yourself

- Explain purpose of the session
- Ensure confidentiality of conversation
- Request appointment card for identification
- Check appointment card with lab slip to ensure match

II. Give Test Result

- Give test result
- Allow client response
- Discuss client's concern
- Explain negative test result
- Discuss recent risk/false negative/need for retesting

III. Risk Reduction

- Formulate plan for future risk reduction
- Discuss risk reduction behaviors:

    - abstinence
    - safer sex practices
    - needle sharing precautions/treatment program
    - importance of not donating blood, plasma, body organs, tissue, and sperm
    - give post-test counseling handout materials and leave the door open for client to return for future counseling and/or testing
    - complete clinic report form

GUIDELINES FOR POSTTEST COUNSELING
POSITIVE TEST RESULTS

I. Introduction

- Review clinic record
- Introduce or reintroduce yourself
- Request appointment card for identification
- Check appointment card with lab slip to ensure match
- Explain purpose of the session
- Ensure confidentiality of conversation

II. Give the Test Result

- Tell the client his/her test result is positive

* **Ask client what he/she thinks a positive test result means**

- Explain the exact meaning of the test result and its implications

* **Ask the client what he/she knows about the virus**

- Explain how the virus can impact or not impact the body's immune system
- Explain which body fluids can transmit the virus and which do not

* **Ask the client what he/she is feeling now that he/she knows the test result**

- Introduce the concept that medical and psychosocial help are available and that you will discuss both in detail at the end of your session together

III. Health and Prevention

- Explain the prevention guidelines

* **Ask the client what behaviors he/she engages in that may transmit the virus**

* **Ask the client what he/she will do to keep from transmitting the virus; what obstacles exist for changing behaviors**

- Reiterate prevention strategies specific to the client

- Explain the importance of maintaining good health

* **Ask the client what he/she can do to maintain good health**

IV. Disclosing Result to Partners and Health Care Provider

- Explain to client that sexual partners and health care providers need to be informed

* **Ask the client how he/she thinks partner will react, offer assistance**

- Explain the option of Notification Assistance Program (reintroduce concept at end of session)

V. Assessment and Referral

* **Ask the client to whom he/she usually turns during difficult times; is this person immediately available?**

* **Ask the client what he/she is planning to do during the rest of the day and during the next few days**

* **Ask the client what he/she is feeling**

* **Ask the client if he/she is thinking of hurting him/herself**

- Offer all referrals both verbally and on paper: mental health provider, crisis intervention, support group, and physician (infectious disease clinic)

- Suggest that the client spend the next few hours or days contacting referrals

VI. Conclusion

* **Ask the client if he/she has any questions**

- Have the client reiterate what changes he/she will be making relative to prevention guidelines
- Reintroduce disclosure issues and NAP
- Collect identifying information on contacts (Partner Referral Form)
- Give handout materials
- Leave door open for the client to return with additional questions or concerns

POSTTEST COUNSELING (PTC) REMINDERS

1. Review clinic record prior to PTC session and never schedule a client who is positive on a Friday or before a holiday.

2. Ensure absolute privacy. Never PTC with someone else in the room. Family or friends could be brought in after individual counseling is completed and only at the request of the client. Counselor trainees may attend PTC only with permission of the client.

3. Make sure you are speaking with the correct individual. Any document the client has to obtain should match the one in your hand by name and/or code number.

4. Introduce yourself and explain your role. Do not PTC an intoxicated or drugged individual. Explain to client in a non-judgmental manner the importance of understanding the information you have to give and arrange for a time when the client can return unintoxicated or not drugged.

5. Provide test result and ensure adequate understanding of its meaning. Here are some examples: 1) Your test result came back positive. Do you understand what the result means? Let the client answer and then explain the meaning of the test. 2) Was this the test result you were expecting? 3) Do you know how you may have been exposed to the virus? After letting the client answer to each individual question, take the opportunity to ask the client how he or she is feeling and acknowledge the feelings.

   Note: If client's test result has come back inconclusive, explain that the test will need to be repeated. Conduct a pretest counseling session, obtain a signed patient pretest information form, and complete a lab form for repeat test.

6. A positive test result triggers an understandable and enormous fear of premature death. Shock and feeling out of control or overwhelmed manifests differently in different clients—tears and sadness, anger, denial, expressions of hopelessness, or even a flat affect in which the client responds to information in an emotionless manner. Help the client to focus on aspects of his or her health and well-being that are within his or her control. Ask about current habits and then discuss avoiding further exposure to the virus, eating right, exercise, reducing drug and alcohol intake, stress, and techniques for stress reduction.

7. Assess immediate problems and prepare for referrals: Evaluate client's level of emotional distress by asking questions that will illuminate immediate problem areas. Such questions should help the counselor evaluate what kind of support system the client has, and if the client is engaging in suicidal ideation.

   Example: Assessing the client's support system:

   - Do you have somebody you feel close enough to that you can share what's going on in your life?
   - Who are the people most important to you? Are you in contact with them?
   - How do you think they would react if you told them about your test result?

   Example: Assessing suicidal ideation:

   - How do you usually spend most of your time?
   - What are your immediate plans for the rest of the day?
   - What are your plans for the next few days?
   - Are you feeling suicidal?

If the client responds with a yes or maybe, the counselor needs to explore whether or not the client has a means or plan for hurting him or herself.

Such a discussion should lead up to making all appropriate referrals which for all clients will include a physician, mental health clinic, Hyacinth support (information) group, CTS, and any other appropriate assistance.

8. Should a patient desire that a result be released to a physician or other provider, secure a signed consent to release HIV test results. Indicate result on release form and send a copy to the specified physician. Keep original release form in client's file. Patient identifier and patient HIV antibody result should be sent under separate cover.

9. Patients who test positive must be told that they should refer sex partners and/or needle-sharing partners to CTS. Inform patient of Notification Assistance Program. The Program will contact the specific partners without the patient's identity ever being revealed. The patient must be encouraged to utilize the program if he or she feels unable to contact partners directly.

10. Leave patient with referral list, sex and drug use behavioral modification information, and post-test counseling messages. Do not hand out information on AIDS alone. Such an action may frighten a client into thinking he or she actually has AIDS.

11. Any type of successful counseling depends on the ability of the counselor to be nonjudgmental, supportive and concise. Never rush through information or ask a client more than one question at a time. Remind client that this test result is just one part of his or her total health picture. Just like a person with diabetes who must make certain behavioral changes, beyond those behavioral changes, life can fall back into a routine that doesn't have to be dominated by HIV antibody status.

Chapter 11—Treatment Duration and Patient Retention

J. Thomas Payte, M.D.
Elizabeth T. Khuri, M.D.

Duration of treatment refers to the continuation of methadone maintenance treatment. Decisions concerning duration of treatment are made by MMTP physicians, other staff, and the patient. Such clinical decisions should be based on accumulated data and medical experience, not on regulatory fiat or general policy (Ball and Ross 1991; Cooper et al. 1983).

In thinking about the duration of methadone maintenance treatment and its implications for patients and programs, it is important to keep in mind that recovery from narcotics addiction, both short-term (less than 6 months) and long-term (greater than 6 months), in the new DSM-IV classification (Kreek pers. com. 1992) is dependent on cessation of illicit use of opiates, not on the presence or absence of pharmacotherapy.

Retention in treatment refers to the patient's ability and willingness to remain in treatment over time and is influenced by a combination of patient and program characteristics. Retention is the essential element that produces optimal duration in treatment.

Retention in treatment should be considered to be the product of a continuing therapeutic relationship between recovering patients and their clinics. In addition, decisions on continuing pharmacotherapy with methadone should be made as part of the ongoing process of assessing the efficacy of specific types of treatment. Ideally, programs should be funded not only to treat patients who are receiving methadone but also those who have undergone dose reduction-elimination and are followed in a zero-dose treatment mode. Patients should always be encouraged to remain in continuing treatment; pharmacotherapy should be reinstituted if and when a relapse has occurred, is feared, or is predicted. Patients who have dropped out of treatment and are not receiving pharmacotherapy should be promptly readmitted to the program for treatment if necessary. Feelings of shame, disappointment, and relapse-related guilt, especially for a well-rehabilitated patient who has a close relationship with staff, may impair the patients' willingness and ability to seek reentry to treatment. Therefore, all obstacles to reentry should be minimized.

Strategies for Rapid Engagement in Treatment

Before a program can deal with the problem of retaining patients in treatment, they must first be admitted. Commonly, programs with lengthy and inefficient admission procedures that require multiple delays and appointments lose a significant number of patients between initial contact and the actual admission.

A careful analysis of the obstacles and barriers that exist for patients who seek treatment should be made at the individual program level as well as across the system. In a system where there are four to five potential patients for every available treatment slot, one might question the need to expedite the intake of new patients. Clearly, the need for treatment improvement goes well beyond the admission process.

According to a study by Stark and colleagues (1990), only 59 out of 117 patients who were given appointments when applying for service went so far as to pick up the application forms; out of those only 13 remained in treatment beyond 1 month. Those who were asked to come to the clinic immediately for same-day admission appeared at a much higher rate than those given appointments.

Methadone maintenance patients should be processed quickly and be reassured that they will receive their initial dose of methadone on the day of application if they meet admission criteria. The minimum essentials of the admission process can be outlined and streamlined to facilitate initial dosing with methadone when needed. The more detailed and extensive elements of the admission process can then be taken care of in a more relaxed manner if the patient is not suffering from acute abstinence syndrome.

While methadone maintenance treatment compares very favorably with other treatment modalities in terms of patient retention, it must be pointed out that retention within methadone maintenance treatment has diminished over the years. The changing patient population, with its multiple addictions, coexisting ADM disorders, and serious medical illnesses, provides a greater challenge to programs that are barely surviving and, in many cases, are attempting to operate as they did in 1980.

Duration of Treatment

Condelli and Dunteman (1991) make it clear that controversy on duration of treatment remains from a policy and regulatory point of view. Because of the high relapse rate to heroin (Ball and Ross 1991) and the risk of acquiring and spreading HIV infection, some feel that addicts should be encouraged to remain in methadone maintenance treatment indefinitely. Another group feels that addicts should be discouraged from remaining in methadone maintenance treatment over a long period on the basis of a belief system that generally rejects any kind of pharmacotherapy in treating addiction. This opinion is usually based on a fear that methadone maintenance treatment somehow discourages addicts from leading drug-free lives. The third group believes that there should be no policy because patients vary widely in how much treatment they need and for how long. According to this position, such decisions are individual clinical determinations and not a matter of public or private policy.

Hubbard and colleagues (1989) state that long-term treatment is a major predictor of positive treatment outcome, while Simpson (1981) has shown that brief treatment episodes (less than 3 months) compare similarly with no treatment at all in terms of outcome. Ball and Ross (1991) tracked the continuing improvement in incidence of IV drug use through the end of the fourth year of methadone maintenance treatment. On the basis of the nearly linear decline in IV drug use to the end of the fourth year, one could expect continued improvement in outcome beyond that point with eventual flattening of the curve.

The Ball and Ross study is but one example of the evidence in favor of long-term treatment, not just in methadone maintenance treatment but in other modalities as well. It is clear that decisions about duration of treatment should be individualized, with any generalization favoring long-term maintenance. In the methadone literature, the terms "long term" and "indefinite" seem to carry the same meaning. Indefinite treatment is appropriate for many patients who fit the criteria for chronic, intractable heroin addiction.

Several studies illustrate the effectiveness of methadone maintenance treatment in reducing the spread of HIV infection among heroin addicts (Batki 1988; Hubbard et al. 1988). A case is made for long-term treatment in looking at the HIV seroprevalence rates among methadone maintenance patients in relation to time in treatment. Those patients in treatment for less than a year have a much higher incidence of HIV seropositivity than those who have been in treatment for several years (Bourne 1988; Nathan and Karan 1989; NIDA 1989).

Yet another consideration relates to addiction as a *disease*. The disease of addiction has been characterized as chronic, progressive, relapsing, and incurable. Any effort to limit duration of treatment for any chronic, incurable, yet treatable disease is obviously inappropriate.

The answer to the complex question, "**How long should methadone maintenance treatment last?**" is simple: **as long as it needs to, or simply, long enough.** Treatment should be continued as long as the patient continues to benefit from treatment, wishes to remain in treatment, remains at risk of relapse to heroin or other substance use, suffers no significant adverse effects from continued methadone maintenance treatment, and as long as continued treatment is indicated in the professional judgment of the physician.

These conclusions are not new. The following paragraph is taken from a discussion summary by Cooper and others (1983):

> The decision to detoxify from methadone maintenance treatment should be made by the patient's physician in conjunction with the patient and other staff. No restriction should be placed on duration of maintenance treatment. (p. 93)

In fact, support for this general principle dates back to the early work of Dole and Nyswander (1966):

> The decision as to whether or not the blockade should be continued...is the responsibility of the physician supervising his medical treatment. The need for continuance [of methadone maintenance treatment] is periodically reviewed. To date we have seen no indication to remove the blockade from any patient in the treatment program.... (p. 2014)

Retention in Treatment

Recognizing that long-term methadone maintenance treatment is appropriate and desirable for most methadone maintenance treatment patients, we now shift

our attention to the matter of retaining patients in treatment for extended periods. Retention, however, depends on the patient entering the treatment system in the first place. In January 1991, the authors participated in a NIDA panel held in Washington, D.C., which addressed program retention and dropout. At that time it was emphasized that there is also a very significant problem with individuals "dropping in" to treatment clinics. The reason why large numbers of heroin addicts fail to make any effort to get treatment must certainly be addressed, in addition to determining the factors that affect retention and prevent dropouts once in treatment.

The literature on treatment retention includes many studies that focus on patient characteristics to predict or explain remaining in or dropping out of treatment. Papers that deal with program factors in patient retention and dropout are unfortunately much fewer. This apparent disparity led one author (Payte) to compare programs to buckets, many of which were leaky and not able to hold water (patients) for any significant period. The abundance of water (patients) allowed the buckets (programs) to remain full and give an illusion of excellent retention. Studies were carried out on the water in an attempt to explain why it was unable to remain in the leaky bucket. While a great deal was learned about water, its ability to remain in the bucket was unchanged. Fortunately, today more attention is directed toward the integrity of the program as it relates to attracting and retaining patients in effective treatment.

In some cases, program staff try to project the responsibility for the bucket's leaks onto the water by using defensive cliches, such as the patient is "not ready for treatment" or the patient is "poorly motivated." It is also true that not all programs are able to remain full despite large numbers of addicts in need of treatment in the program vicinity. The addict should not have to overcome a host of obstacles to enter and remain in treatment. These obstacles cannot be justified as ways of testing patient motivation. Many of these will be discussed below.

It is not intended that the effort to focus on program characteristics should minimize or diminish the importance of patient characteristics. There is no question that the degree of sociopathy, the presence and severity of psychiatric disorders, and a host of other psychosocial factors influence the course of treatment. However, our capacity to deal with program elements is perhaps greater than our ability to influence some very serious patient problems that complicate drug dependence treatment.

Patient retention should be seen as a major objective of treatment for MMTPs. While patient characteristics have been studied extensively in relation to retention and dropout, this chapter will focus more on the program elements that correlate to retention of patients in methadone maintenance treatment.

Program Elements Associated With Improved Patient Retention

The items discussed in this section are an amalgam of the authors' clinical experience and the work of several experts in this field. As would be expected, many arrive at similar conclusions, even those from differing approaches. This list incorporates work done by Ball, Condelli, Caplehorn, Hubbard, Simpson, and others (see references).

Clinic Accessibility

Easy access to clinics is important in retention. Greater distances mean more time and expense associated with travel to and from the clinic. Geographic decentralization is needed in those locations where the addicted population covers wide areas. Access is also a matter of efficient patient flow at a clinic site.

Convenient Hours

Treatment should be rendered in the manner that is least disruptive to patients' travel, work, educational activities, use of supportive services, and family and social activities. Hours should be determined on the basis of patient needs rather than staff preferences. Many suggest that an absolute minimum of 2 hours be available outside the traditional 8 a.m. to 5 p.m. working day. Depending on clinic size and resources, clinics should consider opening at or before 6 a.m., remaining open until 7 p.m. or later, or both. Methadone maintenance treatment should not become a contributing cause to continued unemployment.

Affordability of Care

The long-term nature of methadone maintenance treatment makes it essential that treatment be affordable as well as available to all who need it. Many patients are able to assume a portion of the cost at some time during the course of their treatment. However, when treatment is necessarily the most intensive, patients are usually least able to pay for care. A quality program offering a full range of counseling and rehabilitative services cost more than can be expected from collection of fees. It is important for financing authorities to place a high priority on stable, *long-term* funding for methadone maintenance treatment. Third parties, both private insurance and Medicaid, should be

encouraged to provide extended coverage to suit the patient's medical needs.

Access to Staff

Frequent absence of a patient's primary counselor is often cited as a problem in treatment programs. When patients do not have ready access to medical and counseling staff, they are likely to be discouraged. Large caseloads and excessive paperwork are factors that create problems in this area. In addition, the number and quality of staff, regulation, and overregulation have been cited as factors that reduce patient access to staff. Any obstacles a patient encounters when trying to see his or her primary counselor should be examined and removed if possible.

Quality and Retention of Staff

Staff to patient concordance in cultural, ethnic, and social factors is important. Staff should be able to relate to patients, and patients need to know that staff understand them. Staff should be adequately trained so that patients recognize they are competent. Staff turnover, particularly among primary counselors, is a very real problem for which creative solutions should be sought. "No experience necessary" should never appear in an advertisement for drug treatment counselors of any kind.

Quality of Social Services

Quality of social services is more important than quantity in determining retention. Such services would include family, legal, educational, employment, and financial assistance. Although we will need additional resources and linkages to address the problem, it is cost effective in the long run to provide these needed services.

Full Range of Services

The capacity to offer a full range of services at the program site offers more than convenience to patients. Primary medical, psychiatric, and HIV services improve continuity of care and provide a more holistic and complete service continuum. Experienced MMTP staff are familiar with the problems associated with referring patients to a range of services outside the program. Relatively few patients follow through on such referrals. One of the many reasons for their reluctance to use outside health care services can be an unpleasant experience resulting from ignorance and prejudice on the part of the outside provider. Too often the addictive diseases are labeled as volitional, a result of poor character or "weak will"; thus, the sequelae of this group of diseases are compounded by stigma, feelings of worthlessness, and trivialization by providers.

Adequacy of Methadone Dose

Please refer to chapter 5, which deals with the principles of methadone dose determination in detail. The study by Caplehorn and Bell (1991) clearly demonstrates marked improvement in retaining patients receiving 80 mg or more of methadone daily (see table 1). Reports also show that programs in which patients are aware of their dose of methadone have better retention than those using blind-dosing practices (Condelli and Dunteman 1991).

Staff Attitudes and Program Atmosphere

The promotion of a warm and caring atmosphere in which patients are treated with dignity, respect, and compassion is an often overlooked, cost-free, and effective retention strategy. A good program should be a focus of love and attachment and provide a "safe haven" during the often radical lifestyle changes assumed by the rehabilitative process. Patient reports indicate that this simple and obvious strategy is not widely applied. Patients report that rude, judgmental, and prejudiced treatment is common among treatment programs. No matter what else these programs may have to offer, patients see them as "bad programs."

The kind, caring, and courteous approach can overcome many other program problems, at least in the eyes of the patient. Dingy, rundown physical plants and limited services are seen as relatively minor problems in programs where patients are treated with dignity and respect and are received with a smile from a caring staff person.

Disruption and Long-Term Treatment

A reasonable amount of inconvenience and disruption is acceptable for limited periods to allow for treatment of an acute condition. But as we look to longer and longer duration of treatment, as for any chronic disease, it is apparent that prolonged significant disruption of daily lives and

Table 1. Relative risk of leaving treatment at various dose levels

Methadone dose range (mg)	Relative risk of leaving treatment (percent)
Less than 60	100 (baseline)
60-79	47
80+	21

routines is not acceptable. Therefore, treatment should become progressively less disruptive to facilitate long-term retention.

Disruption may occur in a variety of forms. Financial drain may lead to premature and ill-advised discharge from treatment, and time and travel distance tend to disrupt patient employment and family life. At times, regulations may call for procedures that are no longer indicated but are still required for program compliance. Some have suggested that treatment itself should progress through levels or intensities, becoming increasingly less intense, expensive, and disruptive. Such a system would encourage individualized care in which the patient would receive just what he or she needed, making every trip to the program worthwhile. Progress toward what has been described as "medical maintenance" (Novick et al. 1988) may be a feature of programs of the future.

Summary

Duration of methadone maintenance treatment should be determined by an individualized decisionmaking process based on careful, ongoing evaluation of the efficacy of treatment; duration should not be governed by local, State, or Federal guidelines or regulations. It must be stressed that long-term, even indefinite, treatment is appropriate for many methadone maintenance treatment patients. Various risk-benefit factors should be considered and include the degree of rehabilitation, resources, support systems available, desires of the patient, response to treatment, and environmental components. Particular attention should be given to a deeper understanding of the real motivation of patients who request a discharge from methadone maintenance treatment.

The therapeutic value of retention in treatment has been discussed, as well as some strategies to enhance retention in treatment. In light of the "leaky bucket" concept, programs have not always shown much concern for patients who dropped out of treatment. Often there is a feeling that the relapsing patient will eventually hit a new bottom and perhaps be better motivated to participate in future treatment.

Such attitudes toward relapse have no place in the AIDS-HIV era. Relapse to injecting drug use cannot be justified as some sort of growth experience. Too many clinicians have had patients return to methadone maintenance treatment only to find they had become infected with HIV during the relapse. In these situations, it may be painful to reflect on whether the relapse might have been preventable.

MMTPs have a grave responsibility to do everything possible to improve patient retention, regardless of the number of people waiting for the treatment slots. Rather than recycling the same slot among many patients, efforts should be made to increase the number of slots available.

When programs become barrier free and "user-friendly," we can expect more applications for treatment. Patient acceptance of treatment is often overlooked in program design. If we listen, we can learn a great deal from our patients who, in reality, have the final word.

Recommendations

- Continue treatment as long as the patient continues to benefit from treatment, wishes to remain in treatment, remains at risk of relapse to heroin or other drug use, suffers no significant adverse effects from continued methadone maintenance treatment, and as long as continued treatment is indicated in the professional judgment of the physician; in short, consider indefinite treatment appropriate for many patients who fit the criteria for chronic, intractable heroin addiction.
- Process patients quickly and reassure them that they will receive their initial dose of methadone on the day of application if they meet admission criteria.
- View patient retention as a major objective of treatment.

Recommendations for improving patient retention include the following:

- Make the clinic accessible; geographic decentralization is needed in those locations where the addicted population covers wide areas.
- Render treatment in the way that is least disruptive to travel, work, educational activities, use of supportive services, and family and social services.
- Determine hours on the basis of patient needs.
- Provide affordable treatment to all who need it.
- Ensure that patients have ready access to staff, particularly to the primary counselor.
- Ensure that staff are adequately trained and sensitive to gender- and culture-specific issues.
- Provide high-quality services.
- Offer a holistic and complete service continuum.
- Ensure that patients receive adequate doses of methadone, based on individual patient needs.
- Provide a safe haven and treat patients with dignity, respect, and compassion.

References

Ball, J.C.; Lange, W.R.; Myers, C.P.; and Friedman, S.R. Reducing the risk of AIDS through methadone maintenance treatment. *Journal of Health and Social Behavior* 29 (September):214–226, 1988.

Ball, J.C., and Ross, A. *The Effectiveness of Methadone Maintenance Treatment*. New York: Springer-Verlag, 1991.

Batki, S. Treatment of intravenous drug users with AIDS: The role of methadone maintenance. *Journal of Psychoactive Drugs* 20:213–216, 1988.

Bayer, R., and Koenigsberg, L. Retention rates among methadone patients: An analysis of the New York experience, 1964–1976. *International Journal of Addictions* 16(1):33–41, 1981.

Bourne, P.G. AIDS and drug use: An international perspective. *Journal of Psychoactive Drugs* 20:153–157, 1988.

Caplehorn, J.R.M., and Bell, J. Methadone dosage and retention of patients in maintenance treatment. *The Medical Journal of Australia* 154:195–199, 1991.

Condelli, W.S., and Dunteman, G.H. 1991. Exposure to methadone programs and heroin use. Center for Social Research and Policy Analysis, Research Triangle Institute. Unpublished paper.

Cooper, J.R. Ineffective use of psychoactive drugs—methadone treatment is no exception. *Journal of the American Medical Association* 267(2):281–282, 1992.

Cooper, J.R.; Altman, F.; Brown, B.S.; and Czechowicz, D. *Research on the Treatment of Narcotic Addiction: State of the Art*. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1983.

D'Aunno, T., and Vaughn, T.E. Variations in methadone treatment practices—results from a national study. *Journal of the American Medical Association* 267(2):253–258, 1992.

Des Jarlais, D.C. Retention rates among New York City methadone patients: A response to Bayer and Koenigsberg (letter to the editor). *International Journal of the Addictions* 17 (5):929–930, 1982.

Dole, V.P., and Nyswander, M.E. Rehabilitation of heroin addicts after blockade with methadone. *New York State Journal of Medicine* 66(15):2011–2017, 1966.

Hargreaves, W.A. Methadone dosage and duration for maintenance treatment. In: Cooper, J.R.; Altman, F.; Brown, B.S.; and Czechowicz, D., eds. *Research on the Treatment of Narcotic Addiction: State of the Art*. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1983.

Hubbard, R.L.; Marsden, M.E.; and Cavanaugh, E.R. Role of drug-abuse treatment in limiting the spread of AIDS. *Review of Infectious Diseases* 10:377–384, 1988.

Hubbard, R.L.; Marsden, M.E.; Rachal, J.V.; Harwood, H.J.; Cavanaugh, E.R.; and Ginzburg, H.M. *Drug Abuse Treatment: A National Study of Effectiveness*. Chapel Hill: The University of North Carolina Press, 1989.

Hunt, D.E., and Strug, D.L. Pathways into treatment: A study of the entry process. New York: Narcotic and Drug Research, Inc., 1988.

Kreek, M.J. Effects of drugs of abuse and treatment agents in women. In: Harris, L.S., ed. *Problems of Drug Dependence, 1991*. National Institute on Drug Abuse Research Monograph 119. Rockville, MD: U.S. Department of Health and Human Services, 1991.

Nathan, J.A., and Karan, L.D. Substance abuse treatment modalities in the age of HIV spectrum disease. *Journal of Psychoactive Drugs* 21(4):423–429, 1989.

National Institute on Drug Abuse. Effectiveness of Drug Abuse Treatment as an AIDS-Prevention Strategy. Paper presented at the American Society on Alcoholism and Other Drug Dependency's Third National Forum on AIDS and Chemical Dependency: Integrating AIDS Prevention and Treatment With Chemical Dependency Treatment, Miami, February 1989.

National Institute on Drug Abuse. National Conference on Drug Abuse Research and Practice: An Alliance for the 21st Century. Washington, DC, January 1991.

Novick, D.M.; Pascarelli, E.F.; Joseph, H.; Salsitz, E.A.; Richman, B.L.; Des Jarlais, D.C.; Anderson, M.; Dole, V.P.; and Nyswander, M.E. Methadone maintenance patients in general medical practice: A preliminary report. *Journal of the American Medical Association* 259(22):3299–3302, 1988.

Simpson, D.D. Treatment for drug abuse follow-up outcomes and length of time spent. *Archives of General Psychiatry* 38:875–880, 1981.

Stark, M.J.; Campbell, B.K.; and Brinkerhoff, C.V. "Hello, may we help you?" A study of attrition prevention at the time of the first phone contact with substance-abusing clients. *American Journal of Drug and Alcohol Abuse* 16(1,2):67–76, 1990.

Chapter 12—The Community Effort: MMTPs as Full Community Members

Dorrie Burke

Community resistance and opposition to the establishment and siting of substance abuse treatment programs is a historical phenomenon (Genevie et al. 1988; Lowinson and Langrod 1975; Ruiz et al. 1978). Substantially rooted in fear of the unknown and complicated by strong apprehensions that stem from stereotypes about drug addiction and drug addicts, the so-called "not in my back yard" syndrome is a significant factor that all substance abuse treatment providers must understand and confront. For methadone maintenance treatment providers, the challenge of community relations and education is significant and critical.

Despite more than 25 years of research and practical experience in methadone maintenance treatment of opiate addicts, the public lacks knowledge of the scientific efficacy of methadone maintenance treatment. Misconceptions persist about the nature of narcotics addiction and the critical impact of methadone maintenance in mediating this problem. Although methadone maintenance treatment is associated with substantial improvements in public health and employment and a reduction in HIV risk and criminal behavior, these benefits are often overshadowed by concerns about patient loitering and drug sales that may occur in the vicinity of some large outpatient MMTPs.

Residential and commercial sectors usually view clinics as threats to property value or economic prosperity or both. Further, negative community and political reaction is frequently based on strong ethical beliefs about drug addiction. While community members may be highly supportive of the concept of drug treatment, methadone is viewed by some as a "chemical crutch" or as the substitution of one addiction for another. Consequently, methadone maintenance patients are not considered distinct from street addicts in the minds of community members.

Misinformation about the methadone maintenance treatment modality has endured despite the field's longstanding efforts to educate legislative, health, and community leaders. Opponents of MMTPs have used protest, zoning loopholes, and negative media coverage to prevent facilities from opening or expanding. Political support has ebbed and flowed since the 1970s, remaining inconsistent and unreliable. While it varies from locale to locale, in general community response to siting and expanding methadone maintenance treatment clinics throughout the nation has been unreceptive. This resistance, in addition to threats to existing sites, keeps MMTP administrators mired in unproductive community conflicts.

By drawing from the experience of the mental health community and the drug-free residential treatment sector, the methadone maintenance treatment field has moved significantly toward adopting models and practices in community education and contacts. This work has brought many programs into the mainstream of community service and membership (and has allowed some programs to gain substantial acceptance). A portrait of useful elements follows, providing a broad perspective in developing successful community education and relations practices.

The Importance of Community Relations and Education

While Federal regulations do not mandate community relations or education, some States compel attention to community concerns and issues through operating regulations, zoning, approval, or licensing processes. Certain localities may require MMTPs to provide a specific program plan to avoid disrupting community life and to ensure responsiveness to community needs. Furthermore, some States' licensing and approval mechanisms require community input or support or both for proposed treatment services, as well as "environmental" impact studies and may require that the needs of area residents be established.

Regulatory mandates aside, MMTPs are in the business of treating people and families. In order to achieve stated goals and to operate effectively, MMTPs need not focus their efforts solely on meeting requirements established by oversight agencies. To carry out successful treatment, programs could work with patients not only as individuals but as members of a family, culture, and community. These are the places from which methadone maintenance patients come and in which they seek to achieve reintegration, acceptance, and success.

An MMTP's interrelationship with the community is derived naturally. On the one side, patients bring community issues to their clinic. The problems that confront patients mirror their communities' struggles toward adequate health care, employment, economic viability, basic safety, housing, education, and so forth. Moreover, community context and characteristics have been found to contribute to treatment outcome (Hawkins 1983). It is shortsighted to suppose that methadone maintenance treatment clinicians can effectively understand and treat patients without understanding and knowing their community—its structures, values, and resources. The MMTP that works as an active member of the community not only serves its patients better but fosters a better understanding and acceptance of methadone maintenance treatment patients in the community.

Concurrently, methadone maintenance treatment programs affect communities. As an integral component of the neighborhood system, the MMTP impacts community health, education, and well-being. In many cases, publicly funded methadone maintenance treatment providers rely upon community support to sustain their programs. Assuming that the MMTP serves only its patients and not the larger community is a disservice to all. It is critical for both new and established MMTPs to adopt the philosophy that, as resources for their communities that treat and assist members of their localities, they are committed to understanding and meeting the needs and concerns of the communities they serve and of which they are a part.

Proactive work with communities, particularly with community leaders (political and otherwise), is the natural and practical course. This approach establishes the MMTP as an integral community member and offers an opportunity to prevent and resolve problems that could threaten the program's relationship with its community.

Methadone Maintenance Clinic Placement and Characteristics and the Community

Genevie and coworkers (1988) studied neighborhood and program characteristics associated with negative community reaction to MMTPs in New York City. Their findings suggested that social environment factors, patient characteristics, MMTP administrative procedures, and the physical "ecology" of the clinic are major components that contribute to negative community reaction toward neighborhood methadone maintenance treatment facilities. Aspects such as patient loitering, number of clinics in the area, and proximity to large outpatient hospitals were found to be significantly related to the negative response. Inversely related to negative community reaction were clinic provision of a place for patients to socialize and the portion of patients receiving medication during morning hours.

While further empirical study is indicated from these findings, including extension to nonurban settings, adequate site planning and implementation of a comprehensive MMTP can be improved by fully considering environmental and patient characteristics relative to the community that the clinic will serve. Ideally, the facility's design and structure will be sufficient to accommodate staff, patients, and program functions. Reception space, individual counseling and treatment offices, a dosing area in a semiprivate setting, private areas for meetings and group counseling, and, to the extent possible, facilities for on-site patient activities to limit patient loitering can be available. Potential program sites can be identified, preferably with community input, to minimize clustering of outpatient facilities.

The physical appearance of the clinic can be carefully conceived as well. The clinic building can always be clean and orderly inside and out to distinguish the unit as a professional facility. Surrounding property (e.g., sidewalks, fencing, trash receptacles, signs) can avoid impeding pedestrian or vehicular traffic, and clinic hours can have minimal impact on community traffic patterns. Careful planning of clinic placement and environmental and physical plant details lays the foundation for preempting community resistance and concern.

The Community Relations and Education Plan

Once appropriately sited and situated, methadone maintenance treatment providers can initiate a multifaceted, proactive plan to establish and maintain ongoing relationships with community leaders and systems. This plan can

be tailored to the needs of the specific methadone maintenance treatment program within its unique locality. The following elements are central to this endeavor. These are minimum standards for such a plan; program activities will differ in their specificity and scope.

- Gaining knowledge of the community
- Incorporating goals and procedures and delineating staff community relations roles or assignments
- Initiating interpersonal communication and contacts with community liaisons
- Carrying out community education and service, including patient and staff involvement in community activities and systems whenever possible
- Addressing and following up existing community concerns through an action plan
- Documenting community-oriented program efforts to evaluate, modify, and demonstrate program progress

Individual MMTPs may pursue a range of endeavors that best suit their locale, staff configuration, and patient census. The following menu of alternatives may help programs approach the goal of effective community membership and relations.

Gaining Knowledge of the Community and Its Structures

In the context used here, "community" refers to a group of people of varying background and focus whose link is their common interest in the integrity and quality of a generally defined geographic area and its people. For an MMTP, the community includes the residents, workers, and patrons of the neighborhood in which the clinic is located, as well as those localities from which the program's patients are drawn. The community's "structure" refers to the organizational pattern of the locality: how it is represented and led in government, business, health, education, and other operational systems.

New or established MMTPs should be informed about important community traits, structures, systems, and needs to effectively integrate as a community member. Staff at all levels of clinic operation can be oriented on community characteristics and know who represents the community and speaks its concerns. Some community leaders are human service advocates who can be expected to be supportive; others may be initially hostile; all may be cultivated. Familiarity with community leadership and how community systems and organizations function will provide MMTPs with more extensive knowledge of legislative issues that impact the program and patients, licensing and operational requirements, program siting and zoning matters, and gaps in the delivery of needed services.

Particularly with respect to developing new sites or expanding services, MMTP directors ideally will comprehend fully the licensing process, including which community agencies must be involved, what approvals are required, and how licensing differs from locality to locality, and State to State. It is helpful for programs to identify the level of input and support that is required or advisable from community leaders in licensing, operating, or developing new service initiatives. Service success is far more attainable if the legislative and community leaders' input and support are sought prior to siting and establishing new projects, regardless of the requirements stipulated by law or regulatory procedure. Programs can focus on those community leaders who are friendly to drug treatment and methadone maintenance, and attempts can be made to cultivate a special interaction and level of support.

Primary resources, such as local administrative or governmental offices, the Bureau of the Census, local statistics and health departments, political organizations, The League of Women Voters, and other advocacy organizations, can provide information about a community's population, its demography, the governmental structure, community-based advocacy groups, community representatives, and other important health and social characteristics. Delineating community representatives creates a base from which to establish effective contacts and liaisons. The MMTP can identify elected officials who represent the clinic and its patients at the Federal, State, and local levels; local health, drug policy, education, youth, and social and human service department commissioners or directors; business organization leaders; community planning bodies and health district boards and managers; leaders of grassroots community associations, and tenants and advocacy groups; law enforcement officials and police advisory bodies; and religious and spiritual leaders.

Identifying Community Relations Personnel, Goals, and Procedures

All MMTP staff serve the community by serving the patients; thus, community relations and education are inherently a function of all MMTP personnel. Staff at all levels can be tapped to participate in community relations-related activities. Nevertheless, having a full-time coordinator of community relations efforts is advantageous. If an MMTP is an affiliate or part of a larger institution such as a hospital,

efforts can be made to ensure that the program receives full cooperation from the parent organization's community or public relations department.

To the extent possible, MMTPs can budget community relations coordinators into their staffing configuration and make a strong case for their funding. Community relations personnel can define, organize, and monitor the wide range of community relations activities required by the program; focus on coordinating staff and patient participation in community efforts; represent the program at community functions; establish liaison with community leaders; and develop ongoing and specific community education activities. If funding for dedicated community relations staff is not available, a committed strategy can be developed and implemented in consultation with the SSA, provider organizations, and coalitions to coordinate the community relations and education plan. Having adequate security staff on-site is equally important in identifying and resolving community problems.

The MMTP can develop and support procedures for implementing a community relations plan specific to the configuration and needs of the program within its community. A policy statement can incorporate the program's community relations philosophy and define the broad goals to be accomplished, which at minimum might include the following:

- Establish a liaison with community representatives to share information about the program and community and mutual issues.
- Serve as a community resource on substance abuse and related health and social issues.
- Initiate mechanisms to hear community concerns about methadone maintenance treatment and the program's presence in the community.
- Develop program policies and procedures to effectively address or resolve community problems and ensure that program operations do not adversely affect community life.

Community relations procedures and guidelines may be developed to outline which staff participate, the mode and frequency of contact, the level of community participation in program developments and activities, handling and followup of community complaints and requests for service, catchment areas for patients to be served (including priority placement of community members in community-based facilities), as well as the nature of information to be openly shared or limited in line with patient confidentiality laws. Necessarily, goals and guidelines will be refined to address specific community issues and problems.

Initiating Interpersonal Communication and Community Contacts

Personal contact with individual community leaders as defined previously permits open dialogue, sharing of information about program activities and operations, and discussion of community developments, needs, and problems. Such communication fosters a sense of trust in the methadone facility's willingnes to listen and be honest in its mission and actions, whether or not the liaison can ultimately be called an "ally." Further, personal contact with community representatives encourages leaders to use the MMTP as a resource for substance abuse and health issues and as a referral source for community members who are experiencing drug- and health-related problems.

Regular meetings with key officials can be held in their offices but need not be limited to that setting. Demystification of MMTPs best occurs when they are viewed in person. Community liaison visits to the methadone maintenance clinic may offer the opportunity to observe operations and speak with staff and consenting patients. Tours of clinics should be carefully planned to provide an accurate understanding of the program and its operations and ensure unimpaired clinic operation and patient confidentiality. Having patients support and participate in such efforts is invaluable, providing the occasion for leaders to witness the real and human nature of methadone maintenance treatment. Clinic tours for visiting professionals and service providers also foster better understanding of methadone maintenance treatment in the community served, resulting in better coordination of care for patients in the community.

In the early stages of developing a community relations plan, a community liaison or advisory board can be beneficial for the MMTP. A group of selected community leaders and representatives may meet monthly or quarterly as necessary to review program changes, program needs, and community concerns and to exchange relevant and requested information. This mechanism provides community officials with a direct avenue to communicate their views and make recommendations about program services or policies in addressing specific community deficits or problems.

Community relations or administrative staff attendance at regularly scheduled community meetings, particularly those that discuss community planning and operational issues or problems, can provide valuable contact and communication with community representatives.

Educating and Serving the Community

The public is entitled to, and can benefit from, information about methadone maintenance treatment and the clinic in their neighborhood. Methadone maintenance treatment providers may establish a continuum of activities to foster community awareness and education, promote accurate information about methadone maintenance treatment, ensure local support and understanding of program operations and services, and address negative community perceptions and problems.

A speakers bureau of program staff may be formed to participate in community health fairs, community events and conferences, community group meetings, career days in schools, and other community functions. These speakers could provide specific information about the program, as well as general information on substance abuse, methadone maintenance treatment, and health matters. Interested "successful" methadone maintenance treatment patients, organized methadone maintenance patient family groups, and methadone maintenance patient "alumni" clubs can be identified and promoted as potential speakers for community groups as well.

Information about methadone maintenance treatment and the program can be presented to the community through various media. A program newsletter that highlights health and substance abuse issues and contains clinic information and patient and staff articles can be published and distributed to community leaders, contacts, and liaisons by mail or at community events. Informational and descriptive program brochures can be developed, as well as periodic press releases about a specific program activity, accomplishment, announcement, improvement, or event. The program's annual report, or its highlights, can be released to selected community officials. The program can choose to participate in media coverage (e.g., print, television, radio) of substance abuse issues by providing staff or consenting patients or both for interviews, or, in carefully evaluated circumstances, by allowing media teams to film specified program activities.

MMTPs may want to take a more aggressive, proactive stance in community projects and events. Sponsoring community conferences and health or substance-abuse awareness events for community residents and families establishes the program as a leader, a resource, and a full participant in educating and serving the community. MMTP staff with expertise in community development can provide technical assistance and support for community organizations and leaders in developing advocacy, health, and support groups; organizing promotion efforts, such as voter registration; and obtaining neighborhood development or improvement grants. Programs can institute projects that provide direct and noninvasive medical screening services (e.g., blood pressure, pulse, weight checks, nutritional advice) to community members free of charge. Hospital-based MMTPs and those licensed to provide primary medical services can assume substantial roles in improving public health by furnishing immunizations for influenza, measles, and other such conditions to community residents and families. MMTPs can give surplus office items or donations of toys or other products from outside sources to needy community organizations. Consenting patients and staff can organize and support projects such as community cleanups and neighborhood patrols. Highly visible patient service to the community demonstrates the MMTP's contribution to community improvement and helps counter stereotypical notions about persons with substance abuse histories.

To further relationships and alliances with other treatment professionals and members of the service community, MMTP administrators and staff can be active as representatives, speakers, or planners at professional conferences and involved as members or leaders or both in professional coalitions and committees, including advisory councils. Such professional affiliations augment community relations efforts through increased professional education and public awareness of substance abuse and methadone maintenance treatment issues, as well as effectively interfacing treatment modalities. These forums also offer the opportunity to share community relations successes and refine models for the methadone maintenance treatment field. Staff participation on local community-based planning or development bodies affords the program the opportunity to contribute to the community's growth and improvement, particularly in social and health service promotion.

MMTPs also serve communities by providing treatment for community residents and offering jobs for qualified community members. Admission policies can be developed, where possible, to assign patients to the facility closest to their home or workplace. Priority placement may be offered to community residents. Efforts can be made to recruit and hire responsible personnel from the community as well.

Taking Actions That Address and Follow Up Community Concerns

The best intentions to educate, serve, and garner community

support are undermined if careful attention to followup is not applied to prevent and resolve community problems, complaints, and concerns. Detailed strategies and procedures can be developed and enacted to identify sources of community anxiety, fear, and hostility. Active liaisons with community leaders and residents can encourage expression of problems that may differ from city to city, and State to State.

Of special importance to the methadone maintenance treatment sector are the issues of patient loitering, diversion of methadone, and drug sales in the vicinity of methadone maintenance clinics. It is helpful for methadone maintenance treatment providers to take steps that may include staff or security tours or both, institution of community hot lines, and other procedures to effectively monitor the areas immediately surrounding the clinic, as well as adjacent residential, business, or recreational areas. Early identification of loitering and other such behaviors affords the clinic an opportunity to curtail the problem before it reaches proportions prompting community complaint.

Staff "rounds" can be considered, particularly on days when the majority of patients are scheduled to visit the clinic. These will provide the opportunity to observe areas at which patients may congregate, such as local parks and fast food establishments. With respect to patient confidentiality, the emphasis of these tours should be observational, not interventional. Logs of reports summarizing staff patrols should be maintained. Staff conducting community tours may visit with local merchants or representatives to show interest in community concerns, as well as to seek out information on loitering and other such problems. Staff visibility serves to remind patients of the negative impact of loitering and similar behavior and to demonstrate to community members the program's active commitment to community safety and well-being.

Patients observed to be involved in unpurposeful or illegal behavior in the community can be identified. The MMTP may develop detailed and consistent policies and procedures that address patient loitering, diversion, and drug sales. First and foremost, these policies and procedures can correctly identify loitering as a clinical issue, which becomes an administrative problem if done repeatedly or by significant numbers of patients. Patient loitering and illegal behavior in the community are indications of the patient's life status or progress in treatment and have implications for the clinical treatment process. The patient may be a loner who has unstable housing and is unemployed; the patient may go to local parks to drink; the patient may loiter for the purpose of socialization or may still be actively involved in drug sales or purchase. For some patients, loitering may be a manifestation of homelessness or lack of daily routine. Programs that experience difficulty in managing patient loitering should investigate the potential funding and development of day treatment to provide structure and an increased level of treatment intensity.

Patients who are observed loitering can be purposefully counseled as appropriate to the nature of the incident. A treatment plan can be developed that involves redirecting such behavior and documenting such efforts. Repeated loitering, despite treatment plan revision, could subject the patient to loss of clinic privileges, transfer, or placement in a more appropriate treatment setting.

Patients observed selling drugs or methadone medication in the clinic vicinity or neighborhood should be discharged. While counter to the mandate of voluntary treatment, patients unwilling to assist program efforts to maintain the clinic's community acceptance may be transferred to another treatment facility equipped to manage the patient's individual behavioral aspects.

Patient discharge is often effective in eradicating the negative impact of loitering and other behaviors on the MMTP in the community and is even suggested by some States in addressing community concerns. Discharging patients for loitering can be considered; however, such decisions should balance consequences for the individual patient and the public health against the need for programs to ensure stable clinic environments and keep community-based services open for all community patients. Loitering policies culminating in patient discharge might provide for "progressive discipline" and incorporate the patient's right to fair hearing and treatment in the disposition process.

Local community representatives can be given the program's business card indicating staff members and a telephone number to call in the event of loitering or other problems thought to involve methadone maintenance treatment patients. However, the program should clarify the role it can assume in responding to calls from the community for assistance, so as to mitigate community representatives' expectations. It should be emphasized that programs cannot assume a police role in resolving such matters; in emergency and criminal matters, the police should be contacted, not the clinic. All patients identified as engaging in loitering and other such behavior can be intervened with at the clinic.

The MMTP's liaison with the local precinct, community patrols, and law enforcement personnel can be critical to smooth community

relations, particularly for programs seeking to address loitering and similar problems. While the police are generally supportive, programs can establish effective relations to counter some law enforcement officials' misperception of the methadone maintenance treatment facility as a foe. Efforts can be made to differentiate those in treatment from active drug users and to help police to view the MMTPs as an ally in their job. Police could be educated about the MMTP's operations, with the understanding that police and treatment programs share the similar purpose of addressing substance abuse in the community. Community problems (e.g., drug sales) identified through staff tours can be reported to the appropriate law enforcement authorities. Local officers can be encouraged to communicate with the program regarding problems potentially involving program patients. Confidentiality being paramount, this relationship can be carefully cultivated and delineated with full understanding of the MMTP's commitment to patient confidentiality.

All community complaints, regardless of validity, can be regarded and responded to seriously. All MMTP action following community complaints can be documented. Whether reported by community members verbally or in writing, the MMTP director or assigned community relations coordinator can acknowledge receipt of the complaint orally and indicate in writing, whenever possible, the program's intention to investigate and follow through with resolving the problem. Staff can arrange to meet with relevant community liaisons to discuss the matter, if necessary, and encourage community representatives to recommend possible solutions. Within the bounds of patient confidentiality, disposition of the complaint can be reported and followed up in writing, with relevant program actions or limitations to action summarized.

Documenting Community-Oriented Efforts

Program efforts to establish productive community contacts, education, and services, and to resolve community concerns can be documented. A data base of information on community relations can be developed and regularly updated. Often, residence data can demonstrate to community leaders that patients are actually community members. Statistics can be maintained on patients' residences (e.g., summaries of address by zip code, planning board, health district, etc.), staff tours of neighboring areas, the number of patients routed into the program's loitering policy, the number and nature of community complaints received, and patient discharge related to loitering, diversion, or other community incidents.

Visits to local representatives or community merchants can be logged and summaries written of staff participation in community contacts and events. Particularly, letters and communications substantiating community complaint and followup can be retained.

MMTP administration can regularly evaluate documentation of community relations efforts. Over time, analysis may suggest deficient areas in making community contacts or resolving problems that require revision in program policy or practice. This information exists as an important body of evidence demonstrating the MMTP's commitment to serving, interacting, and working as a full community member.

Summary

As members of communities that both serve and influence community life, MMTPs can direct activities and programming beyond established clinic bounds. Traditional community opposition and resistance to MMTPs and their patients prompt attention to a comprehensive approach to community contact and community relations. MMTPs can dedicate goals, procedures, and effort to establishing an effective community relations plan relevant to appropriate siting of clinics and knowledge about the community's representatives and systems. This plan can include significant interpersonal communications and contact with community leaders, community education and service activities, resolution of community concerns, and documentation of community-oriented program efforts. These efforts, if engaged in systematically and comprehensively, can serve to establish the MMTP as an accepted and vital community member.

Recommendations

- Consider community need and impact in siting programs.
- Ensure that the clinic's physical appearance is clean and orderly and that the physical setting does not impede pedestrian flow.
- Identify community leaders (representatives of the district within which the clinic is situated, as well as those districts served), and establish interpersonal contact, liaison, education and/or proactive association with the following people:
  - Publicly elected representatives
  - Local health, substance abuse, social, and/or human service agency directors
  - Business organization leaders

  - Community and health planning agency directors
  - Grassroots community organization leaders
  - Local police and law enforcement officials
  - Religious and spiritual leaders
- Develop and support a community relations plan specific to the configuration and needs of the program within its community.
  - Establish a liaison with community representatives to share information about the program and community and mutual issues.
  - Identify program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan.
  - Serve as a community resource on substance abuse and related health and social issues.
  - Initiate mechanisms to hear community concerns about methadone maintenance treatment and the program's presence in the community.
  - Develop program policies and procedures to effectively address or resolve community problems (including patient loitering and methadone diversion), and ensure that program operations do not adversely affect community life.
- Document community relations efforts and community contacts, evaluate these efforts and contacts over time, and address outstanding problems or deficiencies.

References

Genevie, L.; Struening, E.L.; Kallos, J.E.; Geiler, I.; Muhlin, G.L.; and Kaplan, S. Urban community reaction to health facilities in residential areas: Lessons from the placement of methadone facilities in New York City. *International Journal of the Addictions* 23 (6):603–616, 1988.

Hawkins, D.J. Community characteristics associated with treatment outcome. In: Cooper, J.R.; Altman, F.; Brown, B.S.; and Czechowicz, D., eds. *Research on the Treatment of Narcotic Addiction: State of the Art.* National Institute on Drug Abuse Treatment Research Monograph. DHHS Pub. No. (ADM)97-1281. Rockville, MD: U.S. Department of Health and Human Services, 1983. pp. 680–700.

Lowinson, J.H., and Langrod, J. Neighborhood drug treatment centers, opposition to establishment: Problem in community medicine. *New York State Journal of Medicine* 75(5)(April):766–769, 1975.

Ruiz, P.; Langrod, J.; and Lowinson, J.H. Community acceptance of addiction treatment programs: A contemporary perspective. In: *Critical Concerns in the Field of Drug Abuse: Proceedings of the Third National Drug Abuse Conference, 1976.* New York: Marcel Dekker, Inc., 1978.

Epilogue—A Personal Retrospective and Prospective Viewpoint

Mary Jeanne Kreek, M.D.

This volume of *State Methadone Treatment Guidelines*, the culmination of an effort sponsored by the SAMHSA Center for Substance Abuse Treatment and chaired by Mark W. Parrino, is urgently needed by policymakers, clinicians, and administrators nationwide to explain both what is being done and what can and should be done to appropriately treat heroin addiction by using methadone maintenance treatment. It is hoped that this volume will also serve to convince diverse groups of readers that it is fiscally and ethically prudent as well as humane to assure access to methadone maintenance treatment of excellent quality for all heroin addicts who are willing to accept and receive such treatment on a long-term basis.

The various writers and reviewers of these guidelines are all seasoned experts who have been involved in various aspects of developing, providing, or critiquing methadone maintenance treatment for many years. The collegiality with which the task of creating these guidelines was conducted exemplifies the esprit de corps that has developed in our field of treatment, prevention, and research concerning the addictive diseases. This ability to work closely and, when necessary, to develop a consensus, with a common spirit underlying all of the efforts, may arise in part from the correctly perceived need to counteract negative attitudes about being involved in treatment or research in this field and from the recognition of the stigma placed on the patient population served. Also, our colleagues in this effort are all keenly aware of the limited and diminishing resources available to achieve the common goals of increasing our knowledge concerning the basis of addiction and providing humane care to those already afflicted with an addictive disease.

It is hoped that these guidelines will be used, modified, and extended as knowledge and situations change and yet will retain their thoughtful and concerned tone to promote the development and nurturing of excellent MMTPs that are accountable to the public on the basis of performance and outcome, rather than on fiscal or procedural assessments alone.

Reflections on the Early Methadone Maintenance Research (1964–73)

As recounted in detail in the second chapter, Professor Emeritus Vincent Dole, then an active clinical and laboratory investigator at the Rockefeller University, was named the Acting Chairman of the Narcotics Subcommittee of the Health Research Council of the City of New York by Dr. Lewis Thomas in 1963. Dr. Dole, assessing the health care needs of the city at that time, concluded that the major health problem confronting New York City and the Nation, both in human and fiscal terms, was heroin addiction. He decided to change the efforts of his own laboratory, which were then focused on hypertension, lipid metabolism, and obesity, to address the problem of heroin addiction. In subsequent years, he decided to turn his efforts to another addictive disease, alcoholism. He recruited the late Dr. Marie Nyswander, who had extensive experience in attempts to treat heroin addiction while a staff member at the U.S. Public Health Service Hospital in Lexington, Kentucky, the Bellevue Hospital in New York City, and in other capacities as a psychiatrist. Dr. Nyswander, who had written *The Heroin Addict as a Patient*, a book that became very meaningful to Dr. Dole, joined him in January 1964.

In autumn 1963, Dr. Dole came to the New York Hospital-Cornell Medical Center (with the permission of the chairman of the Department of Medicine) to recruit one or two first-year medical residents interested in joining him at the then-named Rockefeller Institute for Medical Research in the initial research efforts on treating heroin addiction. After a lengthy interview process, I was fortunate to be selected. I had the privilege of joining Dr. Dole as the first house officer in internal medicine at the New York

Hospital-Cornell Medical Center program to be allowed to do a formal research elective (which started in early 1964) at what was subsequently renamed The Rockefeller University.

Dr. Nyswander became mentor to Dr. Dole and me. We began to learn about the behavioral and medical problems of the heroin addict, and, most important, we learned from Dr. Nyswander to listen to the patients. As all three of us assimilated the available published literature on opiate pharmacology, we formulated both the questions to be asked and the goals of our initial efforts. The first goal, the most urgent and specific, was to develop a new approach to treating opiate addiction that would have at least a moderate degree of success. The specific research questions articulated related in part to this pragmatic need but primarily asked the much more fundamental question, which my own laboratory and many others are still addressing: What are the biological bases of the addictive diseases?

Careful scrutiny of the then-available clinical literature, including both studies and anecdotes, made it quite clear that less than 30 percent of "hard core" long-term heroin addicts had ever been successfully treated by any of the methods used up to that time. Primarily, these approaches consisted of various modes of "drug free" or abstinence-oriented treatment, as well as attempts at treatment with short-acting opiates, such as heroin itself or morphine. These early studies, which were few, included rigorous followup studies of all volunteer and prisoner patients who had entered the U.S. Public Health Service Hospital and Research Unit at Lexington, Kentucky, from 1936 to 1941 and prior studies in this country and in Europe. All of these studies suggested to us from the beginning of our work together that there might be a metabolic basis for heroin addiction.

In more recent years, our laboratory group, along with others, has modified that hypothesis to suggest that there may be a metabolic basis for opiate addiction and other specific addictive diseases and that such metabolic bases may include drug-induced alterations of neurochemistry, in particular, changes in ligand-receptor systems that persist over long periods or become permanent. In some or most cases, there may also be an underlying genetic predisposition or vulnerability to addiction after initial exposure to specific types of drugs or other chemical agents of abuse.

Our first goal in 1964 was to repeat earlier studies performed at Lexington and various other treatment research centers that attempted to use short-acting narcotics, such as heroin or morphine to manage opiate dependency. As with all other earlier studies, morphine was promptly shown (within a few weeks) to be an unsuitable pharmacotherapeutic agent because of its short duration of action, requiring the administration of 4–6 doses of medication per day; its lack of substantial systemic bioavailability after oral administration, leading to the need for parenteral administration of the drug; and the rapid tolerance for it that develops. The desired effect of morphine—preventing narcotic abstinence withdrawal symptoms—required regular increases in the doses administered (parallel to the tolerance to the analgesic or pain-relieving effects that occur when morphine is given on a chronic basis to pain patients). Other desired end points of an effective pharmacotherapy, including reducing or eliminating "drug hunger" or craving and reducing or eliminating drug-seeking behavior and illicit use of drugs, could not even be studied in this setting because of the pharmacodynamics of a short-acting drug (morphine) and the rapid and ever-increasing development of tolerance.

The Development of Methadone Maintenance as a Treatment Modality

Early on in our work, we conceptualized the ideal pharmacotherapeutic agent for treatment of heroin addiction. It would be a drug that would (1) have the pharmacokinetic profile of a long-acting drug in humans, thus providing sustained plasma levels over a prolonged period (ideally, 1 day or more, related to a plasma terminal half-life of 24 hours or more) and (2) be orally effective, both to remove the addict from the real risk of exposure to diseases (then "infectious" hepatitis, now hepatitis B, C, delta, and HIV-1 infection) and to diminish the behavior of congregating to share syringes and needles, with drug use being the only basis of those relationships.

In 1964, no adequately sensitive and specific analytical technologies, such as gas-liquid chromatography, mass spectrometry, high-performance liquid chromatography, or radioimmunoassay techniques were available to measure plasma or blood levels of exogenous opioids such as heroin; its major metabolite, morphine; or methadone. Clinical observations alone had to be used to assess the relative duration of action of these drugs.

Methadone had previously been studied by several groups as a potential analgesic agent, and these studies suggested that it was short-acting, with a duration of action for pain relief similar to that of morphine or heroin. However, previous clinical experiences, such

as those Dr. Nyswander had at Lexington and Bellevue Hospitals in New York City, and those I had as a Columbia University medical student working on the opiate detoxification wards at Bellevue, had suggested to us that methadone might have a longer duration of action for the desired effect of preventing opiate withdrawal symptoms. Also, some careful studies on the potential use of methadone for the relief of pain had suggested that repeated doses of methadone during a 24-hour period caused apparent drug accumulation, leading to the undesired effect of respiratory depression. These limited clinical experiences, using methadone for both detoxifying opiate addicts as well as managing pain patients, suggested that methadone was orally effective, that is, that it had significant systemic bioavailability after oral administration. Therefore, it was decided to determine if methadone could be used to stabilize former active heroin addicts on a single, daily, steady oral dose, thereby simultaneously preventing withdrawal symptoms, drug hunger or craving, and drug-seeking behavior with the resultant illicit use of heroin.

The rest of the early history of our research efforts and the first introduction of methadone as a treatment modality for heroin addiction has been detailed in these guidelines and in the clinical research literature. We experimented with a treatment regimen consisting of a methadone dose of 20–40 mg orally per day, delivered in a single dose; an initial dose that depended on the estimated degree of tolerance and dependence already developed by each patient as evaluated individually; and, after induction into treatment, an increase in that dose by small increments once or twice each week, up to a stabilizing dose of 60–100 mg of methadone a day. After initiating this treatment, we found that the former heroin addicts displayed neither signs of narcotic abstinence nor signs of any narcotic effect, such as euphoria or somnolence (sleepiness), even at the time of peak drug effect.

When initial methadone treatment doses are appropriately chosen and then increased at a sufficiently slow rate so that tolerance develops following each increment, no narcoticlike effects should be perceived by a patient in methadone maintenance treatment. Similarly, in most subjects, both in these early studies and numerous subsequent studies, it was found that narcotic withdrawal symptoms are prevented for a 24-hour dosing interval. However, in some patients, withdrawal symptoms may appear before the end of the 24-hour dosing interval because of severe chronic liver disease. Unexpected findings of later studies showed that, in patients with severe chronic liver disease, the systemically bioavailable amount of methadone is actually reduced because of reduced hepatic storage capacity for methadone, despite the fact that hepatic biotransformation may be slowed. Alternatively, this reduction occurs because of metabolic drug interactions, such as those that occur with chronic heavy use or abuse of alcohol or with use of therapeutic agents such as phenytoin or rifampin, that accelerate the biotransformation of methadone by enhancing microsound enzyme capacity.

Early Studies on Methadone's Interaction With Illicit Drugs

The earliest studies using methadone, which were initiated in late February 1964 and performed throughout the next several months, documented that methadone could be effective, when administered in a single oral dose each day, in preventing withdrawal symptoms and so-called "drug hunger" or "craving," specifically for use of opiates. An early question our small research team asked was whether or not a former heroin addict so treated would be in jeopardy upon returning to the streets; that is, Would the addict possibly suffer an opiate overdose if an illicit dose of heroin, superimposed on the background of methadone maintenance treatment, were self-administered?

Therefore, two separate 4-week sequences of rigorous clinical research studies were performed on the basis of a random order (Latin-square design protocol) in which heroin, morphine, hydromorphone (Dilaudid), methadone itself, and saline were injected intravenously in escalating doses against a background of steady-dose methadone maintenance treatment, with both the subjects and the clinical investigator blinded (i.e., "double blinding") throughout the studies until the entire sequence of studies was completed. When the code was broken at the end of these studies, it was found that the former heroin addicts did not perceive any effect following IV injection of these narcotics, with the exception of those days when morphine was administered. On morphine administration days, the sensation of "pins and needles" was reported by the study subjects, who then would inquire: "Where is the high?" and "Where is the euphoria?" since no narcoticlike effect followed the "pins and needles" sensation, as would have been anticipated on the basis of their previous experiences when not receiving methadone maintenance treatment.

From these studies, we learned that the degree of narcotic tolerance developed by the maintenance doses of 60–100 mg of methadone per day also provided a cross-tolerance to other narcotics. That is, short-acting narcotics, such as heroin and morphine, in dose

amounts similar to or even greater than those that might be used illicitly on the streets, would not result in any perception of a narcoticlike effect.

These clinical research studies, conducted in our controlled setting at the Clinical Research Center of The Rockefeller University Hospital, have been repeated possibly more frequently than any other clinical research studies in the history of medical science. However, most of these "repeat studies" have been carried out on the streets, as subjects attempted to see if they could override the so-called "blockade" provided by methadone-induced tolerance and cross-tolerance through adequate dose treatment. This blockade of acute desired euphoria effects or "high" following illicit self-administration of heroin or any other short-acting narcotic serves as an additional treatment mechanism by classical "deconditioning" and is followed by the extinction of drug-seeking behavior by methadone-treated former heroin addicts. This effect is the basis of a separate, yet concomitant, behavior-based therapeutic approach suggested earlier by A. Wikler (U.S. Public Health Service Hospital, Lexington, Kentucky). From 70 to 80 percent of all our earlier and current subjects made or will make the decision to give up the narcoticlike effects or "high" that may be achieved after administering short-acting narcotics, such as heroin, without methadone maintenance treatment for the feelings of normalcy provided by steady-dose methadone maintenance treatment. As determined by subsequent rigorous clinical research studies, physiological normalization also occurs during steady-dose, long-term methadone maintenance treatment.

Highlights of Research on Methadone Maintenance Treatment (1973–92)

Although even at the time of our initial studies in 1964 we frequently discussed in theoretical terms the probable existence of specific opiate receptors, these were not to be fully described until 1973 by S. Snyder (Johns Hopkins University), E. Simon (New York University), and L. Terenius (University of Uppsala, Sweden). The early work of V.P. Dole (The Rockefeller University), W. Martin (U.S. Public Health Service Hospital, Lexington, Kentucky), A. Goldstein (Stanford University), and others all contributed to the ultimate elucidation of the existence of specific opiate receptors. We now know that at least three types of specific opiate receptors exist: mu, delta, and kappa, each of which may have several subtypes. We also know that methadone binds primarily or exclusively to the mu type of opiate receptors. As used in appropriate maintenance treatment, methadone provides a perfusion of these receptors in a steady state fashion.

By the early 1970s, studies using analytical techniques developed by my group, as well as others, showed that plasma levels of methadone are sustained in a relative steady state over a 24-hour dosing interval and that peak plasma levels of methadone reach barely a twofold increment over the steady state levels. The smooth pharmacokinetic profile of methadone, when used on a steady, adequate-dose basis, is sharply distinguished from that of morphine or heroin and thus provides steady state perfusion at specific opiate receptor sites.

This steady state opioid perfusion during methadone maintenance treatment appears to allow normalization of many physiological functions that are significantly deranged by the "on-off " effects of short-acting opiates such as heroin. Some important physiological functions that are deranged during cycles of heroin addiction include the stress responsive system of the hypothalamic-pituitary-adrenal axis; reproductive biology hormones of the hypothalamic-pituitary-gonadal axis; and various indices of immune function that are linked to, or modulated by, neuroendocrine function. Also, gastrointestinal function may be significantly altered by short-acting opiate use by virtue of the opioid receptors in the enteric nervous system, as well as in the central nervous system sites of control of gastrointestinal motility.

Long-term prospective studies of 3 years or more, designed to examine the medical safety of chronic treatment with methadone, the efficacy of such treatment, the physiological status of heroin addicts entering treatment, and the effects of methadone on physiology when administered on a chronic basis, have yielded many important findings. These findings have provided guides to scientific investigators in exploring the role of the endogenous opioids, or "endorphins" (i.e., the body's own opiatelike compounds, including the enkephalins, dynorphins, and beta-endorphins) in normal physiology, as well as in pathological states.

Many studies from our laboratory have been focused on the possible role of this endogenous opioid system (i.e., the endogenous opioid peptides and their specific receptors) in the biological basis of addiction. We have increasing amounts of research-derived information about the role of this system in normal physiology and in

a variety of pathological states. Our data to date suggest that the endogenous opioid system is profoundly disrupted during cycles of heroin addiction and becomes normalized during chronic, steady-dose methadone maintenance treatment. Of considerable excitement are our recent findings suggesting that the endogenous opioid system may also be disrupted by cocaine. Other studies, from both our group and others, suggest that certain indices of the endogenous opioid system may similarly be disrupted by alcohol. Thus, research that began first as part of assessing the safety of chronic methadone maintenance treatment has led increasingly to important clues and substantial information about fundamental physiological processes, the derangement of which may be intrinsic to the biological basis of opiate addiction and possibly other addictive diseases.

As part of our early prospective studies of all patients who entered methadone maintenance treatment from 1964 to 1966, as well as retrospective studies of all who entered treatment up to 1969, we have learned something else that is extremely important: Long-term methadone maintenance is indeed medically safe. To date, methadone has not been shown to cause toxicity to any organ system. Studies continue with vigilance. The longest followup studies, performed on patients in continuous methadone maintenance treatment for at least 10 years, and which soon will be completed and reported, have shown again that methadone is safe to use on a long-term basis.

Growth of MMTPs and Accompanying Problems

By the early 1970s, the early successes of methadone maintenance treatment were beginning to be better known. However, for a variety of legal and cultural reasons (see ch. 2), the established medical community was extremely reluctant to treat addicts with pharmacotherapeutic agents, and the lay public heavily stigmatized such patients. Nevertheless, the obvious successes of methadone maintenance treatment, especially the significant reduction in arrests, encouraged many policymakers, clinicians, and scientists to support the further development of treatment resources and to nurture biomedical research in this area. Thus, in the early 1970s, rapid expansion of MMTPs occurred.

It is necessary to underscore the importance of the many individuals whose leadership resulted in the expansion of methadone maintenance treatment. Chapter 2 cited several of the Federal officials and treatment practitioners who were responsible for building the network of methadone maintenance treatment programs, and many others, too numerous to mention, contributed to this effort as well.

It should be emphasized that patients were first treated at The Rockefeller Hospital, throughout the 1960s, when most of the clinics established were either research projects or early demonstration projects. The staff members, for the most part, were interested in and knowledgeable about their work, and the patients were cared for with obvious concern. Although no Federal regulations existed until 1973, the needs of each patient were usually appropriately addressed through behavioral counseling, rehabilitation efforts and vocational guidance, and medical and psychiatric care, often on-site or through facilitation of access to such care.

However, as Dr. Dole ominously predicted in some of his writings in the early 1970s, methadone maintenance expanded rapidly because of policies obviously predicated on an incorrect view of methadone by policymakers as a panacea that could cure all of the problems of addiction; this view assumed that little more than giving out methadone was necessary. The capacities of clinics were expanded at a rate far exceeding the availability of knowledgeable and caring staff to run those clinics.

At the same time (1973), detailed regulations for providing treatment, which placed emphasis on process and mandated documentation of adherence to process rather than assessment of patient outcome to determine success or failure, were promulgated by FDA, as mandated by Congress. This was the first and only time that FDA ever regulated the use of an approved drug. These regulations controlled details of the medical practice of methadone maintenance treatment, including methadone doses that could be given, and recommended that time in treatment not exceed 2 years. By 1983, these regulations had been revised to eliminate major inappropriate requirements.

The patients with problems related to methadone maintenance were the patients who became easily visible to the lay public. Beginning in the mid-1970s, in many areas, loitering on the streets, diversion of take-home doses of methadone, and inappropriate or criminal behaviors emerged as issues that to a large extent reflected the problems of patients, especially those who had unaddressed concomitant addictive diseases, such as alcoholism or polysubstance abuse, or comorbidity with a behavioral disease requiring psychiatric care.

Sadly but understandably, by the middle to late 1970s, lay public attitudes toward methadone maintenance had become strikingly negative in many regions. Unfortunately, many of these attitudes still prevail. Possibly as a result of these attitudes, and the

philosophical and economic changes over the past 15 years, the funding (in real dollars) for methadone maintenance treatment decreased steadily in most regions. Thus, with steady or even increasing patient loads, decreasing per capita funding, and the emphasis on paperwork decreed by continuously evolving Federal, State, and local regulations and guidelines, excellence in treatment programs eroded further, despite the fine efforts of many physicians, nurses, counselors, and other health care providers who remained in the field throughout the years. Physical sites for clinics deteriorated, and because of increasing expenses, attractive clinics were often relocated to unsuitable locations with unimproved storefronts or to other nonmedical buildings, with no renovations possible.

Growth of Addiction-Related Diseases

Another problem that haunted MMTPs confronted with dwindling resources was the lack of on-site medical care or direct access to medical care needed to manage the medical problems encountered by patients and staff of clinics. By the late 1960s, infectious hepatitis could be defined more correctly as hepatitis B. The injecting heroin addict was identified as being in one of the two highest risk groups for spread and acquisition of this disease, with over 80 percent of the injecting heroin addicts entering treatment having markers of prior infection. By the late 1970s, a second and very dangerous form of hepatitis, caused by the delta agent, a viroidlike agent that requires hepatitis B for its own infectiousness, was identified in retrospect (after the first description of this disease in 1978), by examining sera we had banked from research patients and patients entering treatment for addiction from 1969 onward. We were able to find that delta hepatitis presented itself in our population of injecting drug users in New York City around 1973. The prevalence of this infectious disease has increased: In a study we performed in 1984, around 90 percent of heroin addicts on the street continued to show evidence of having been infected with hepatitis B, as evidenced by the presence of some marker for that disease, and around 30 percent by that time had evidence of hepatitis delta infection.

As is well known to all, in 1981, yet another disease, AIDS, was identified, and shortly thereafter the etiological viral agent, a retrovirus called HIV-1, was identified and characterized. Again, by examining blood samples that had been banked prospectively from 1969 onward, we were able to determine that HIV-1 infection reached the injecting drug-using population in New York City in 1978 and progressed rapidly until 1983–84, when the prevalence of HIV-1 infection reached around 50–60 percent in our region. However, of tremendous public health importance were our findings that of those heroin addicts who had entered an effective methadone maintenance treatment program prior to the AIDS epidemic hitting New York City in 1978, less than 10 percent had evidence of HIV-1 infection (i.e., were anti-HIV-1 positive) in 1984, as contrasted with the 50–60 percent prevalence of HIV-1 infection in untreated heroin addicts at that time. Methadone maintenance was profoundly effective in preventing HIV-1 infection because it eliminated injecting heroin use in over 90 percent of well-stabilized patients, thus eliminating exposure to diseases transmitted through the use of contaminated needles. It also brought about a significant decrement in cocaine use (from 60 to 90 percent prevalence of concomitant cocaine abuse in heroin addicts at the time of admission in many regions down to only 20 to 40 percent during continued methadone maintenance treatment in most reported studies).

Effect of Methadone Maintenance Treatment on Immune Function

Studies performed by my laboratory, and confirmed by others, have shown that in long-term methadone maintenance treatment, immunological function, which is highly deranged in heroin addicts, becomes normalized. This effect is probably primarily due to the cessation of injection of foreign substances and the resulting decreased exposure to diseases but may also be due in part to normalization of endocrine function during chronic methadone maintenance treatment because various hormones modulate specific indices of immune function and because neuroendocrine function is disrupted during cycles of heroin addiction. This normalization of immune function may ultimately be shown to be of importance in altering the rate of progression of HIV-1 infection to AIDS as well as altering, in a favorable direction, the natural history of other infectious diseases, including hepatitis B and hepatitis delta.

Studies on the Biological Bases of Addiction

We have hypothesized that opiate addiction and possibly other addictive diseases may be in part due to atypical responsivity to environmental and behaviorally induced stress. We have also hypothesized that this alteration in stress responsiveness, which we have shown in objective studies of neuroendocrine function in pharmacological agent-free former heroin addicts and in recently

abstinent cocaine addicts, may in fact contribute to perpetuating drug-seeking behavior and drug self-administration. These abnormal responses to experimentally induced stress include disruptions of the normal feedback controls of release of the endogenous opioids and other related stress-responsive and gonadal hormones. Our group and many others will continue to perform studies using animal models, in vitro systems, and basic clinical research settings to determine the role of the endogenous opioids, other neuropeptides, and neurotransmitter systems in the biological basis of addictions.

Many research groups, including our own, are pursuing studies related to the possible genetic basis of addiction. Our own hypothesis is that normal or abnormal alleles of multiple genes, acting in concert, may be involved in creating a vulnerability to addiction once exposed to an addicting agent. At the same time that these extraordinarily exciting and provocative basic laboratory and clinical research studies are progressing, we and many other research groups will continue to search for pharmacotherapeutic approaches to managing alcoholism and cocaine dependency, so that the success in managing those diseases may increase to the level that has been and can be achieved with the appropriate use of methadone maintenance treatment. We also are continuing to look for improved approaches to treating opiate dependency and concomitant addictive diseases, including novel adjunctive or primary pharmacotherapeutic approaches and special combinations of drug-free approaches.

It is clear that a further understanding of the basic neurobiology, as well as the sociological and environmental factors, that contributes to heroin addiction or any of the specific addictions, such as cocaine dependency and alcoholism, may be invaluable, not only for planning new therapeutic approaches to managing these disorders but also for primary prevention.

Factors in Effective Methadone Maintenance Treatment

One of the greatest tragedies now is the all-too-frequent failure to use methadone maintenance as effectively as it may be used. In our early studies from 1964 to 1969 and 1969 to 1973, we repeatedly showed that methadone could be effective in up to 80 percent of former "hard-core" heroin addicts, defined as those who self-administered heroin several times every day for at least 1 year, with development of tolerance and physical dependence. Over 80 percent voluntary retention in treatment for 2 years or more has been found in "good clinics." In those same clinics, it has been shown that less than 10 percent of patients will ever use heroin after the first 3–6 months of stabilization on methadone maintenance. In those "good clinics," the prevalence of cocaine abuse will decrease from 60 to 90 percent of subjects at the time of admission to 20 to 40 percent of patients during steady-dose treatment. It has been shown in earlier times, when jobs were available, that over 60 percent of such patients would return to a job, to school, or to homemaking, and although the percentages are lower now because of the general lack of jobs for which our patients may be adequately trained, the results of rehabilitation efforts are still impressive. In addition, the reduced arrest rate of methadone-maintained patients compared with street addicts has been documented by many studies, as has the reduction in new cases of hepatitis B and HIV-1 during treatment.

As discussed, the earliest studies from our group at The Rockefeller University, subsequent studies, especially those by H. Joseph, V.P. Dole, and D. Des Jarlais, and the much more recent studies by J. Ball and C. O'Brien and their respective groups, have all shown that an adequate dose of methadone must be used to achieve optimal treatment of most patients, especially during the first 2 years of methadone maintenance treatment. During the early treatment months, the tolerance and cross-tolerance effected by the oral administration of 60–100 mg of methadone per day not only prevents narcotic abstinence symptoms, drug hunger, and drug-seeking behavior, but also, through blockade or the cross-tolerance phenomenon, prevents any desired effect from being achieved when illicit, short-acting drugs are coadministered.

Because of negative attitudes and progressively diminishing funding for treatment, ironically coupled with the increased perceived need for treatment and the increased numbers of active heroin addicts seeking treatment, many programs have become so large with such limited staff, both in terms of numbers and training, that the quality of treatment in many clinics has decreased steadily. Also, all too frequently, inadequate doses of methadone are used in treatment. Unfortunately, these problems have sometimes led to a self-fulfilling negative prophecy on the part of those who are passively or actively antagonistic toward methadone maintenance treatment specifically, and pharmacotherapy of addiction in general. The three major factors in successful methadone maintenance treatment, which our earlier studies and the studies of Ball and O'Brien have underscored, are (1) administration of adequate doses of methadone; (2) adequate staff, both in numbers and training; and (3) staff concern for patient

needs, as well as low staff turnover. All three of these factors are associated with improved patient outcomes.

Given the reality of the AIDS epidemic, coupled with the continuing problems of hepatitis B and hepatitis delta and the emerging problems of multidrug-resistant TB and STDs, it is increasingly obvious to those working in "good clinics" that even those clinics need an enhanced ability to deliver primary medical care and to have close linkages for more specialized medical care. In addition, there is a continuing need for primary psychiatric care and for linkages to more specialized psychiatric care to be available. Limited studies on the health-care economics of such models have been performed. Those rough estimates have repeatedly suggested that it would be more economically sound to provide primary medical care and primary psychiatric care, along with counseling and rehabilitation efforts, on-site in methadone maintenance programs than to have fragmented care, which costs more, and which, unfortunately, patients rarely use to the extent needed. Also, the few economic impact assessments that have been performed have clearly shown that it is much less expensive to have a heroin addict in effective treatment, especially good methadone maintenance treatment, than to have an addict either on the streets carrying out criminal activities to support a drug dependency problem or incarcerated. Therefore, even for those policymakers or members of the general public who may not have a humanistic approach to treatment of heroin addiction, the economic facts should be sufficiently persuasive to urge support for developing and nurturing MMTPs of excellence.

Consideration of Current and Future Needs

The essential characteristics of an effective pharmacotherapeutic agent for the addictions have been delineated, and methadone, as used in maintenance treatment, fits all of the specifications. Methadone as an agent (1) is orally effective; (2) is long-acting in humans; (3) has a known and specific site of action; (4) is medically safe to administer on a chronic basis; and (5) has no toxic effects, limited adverse effects, and few undesirable side effects. In addition, the action and pharmacodynamic requirements of such a pharmacotherapeutic agent of an addiction have been elucidated and are also met by methadone as used in maintenance treatment. Again, methadone (1) reduces or prevents withdrawal symptoms, (2) reduces or prevents drug hunger or drug craving, and (3) reduces or eliminates drug-seeking behavior. All of these criteria must be considered as attempts to develop a new pharmacotherapeutic agent for treating cocaine dependency or alcoholism progress.

Twenty-eight years of basic and applied clinical and laboratory research have defined how methadone should be used in maintenance treatment, and that rationale has been backed up by a variety of more fundamental clinical and laboratory research studies. An adequate methadone dose should be used in treatment (usually 60–100 mg/day), and that dose should not be rapidly increased or decreased; increases or decreases in dosage should not be used in "contingency management" to reward or punish a patient for other behaviors. In fact, because of the very slow onset of action, low peak effect, and prolonged duration of action, no cue or signal can be perceived in a timely fashion from such manipulation of dose, and thus, the very purpose for which it would be intended would not be achieved. Rapid changes in methadone dose do, however, serve to disrupt normalization of physiological function achieved by steady-dose treatment. In addition, methadone maintenance treatment programs should have adequate counseling as well as other kinds of support services, including vocational guidance, other types of rehabilitation support, approaches for managing other concomitant addictive diseases, and on-site or ready access to medical and psychiatric care as needed.

The staff of clinics should talk with patients. In any medical disorder, we learn by listening to and observing our patients. This maxim is especially true in the area of the addictive diseases. The more the staff is capable of listening to patients, the more effectively treatment may be tailored to the individual needs of those patients. This principle implies that the staff should be composed of people who can listen and ask questions that may provoke responses that give insights into the specific problems, needs, and other nuances of the disease under treatment. A staff that can listen, question, and observe and, at the same time, provide a spectrum of services usually implies one that is also knowledgeable, concerned, and humane. Less easily measured than blood levels of the pharmacotherapeutic agent, urine content of a drug of abuse, receptor or peptide ligand levels, or the myriad of social and psychological indices measured by multiple and well-validated instruments of psychology and psychiatry are those qualities that make any individual staff member an excellent and humane care provider.

The greatest needs with respect to methadone maintenance treatment now begin with the need to change general public attitudes and therefore the attitudes of

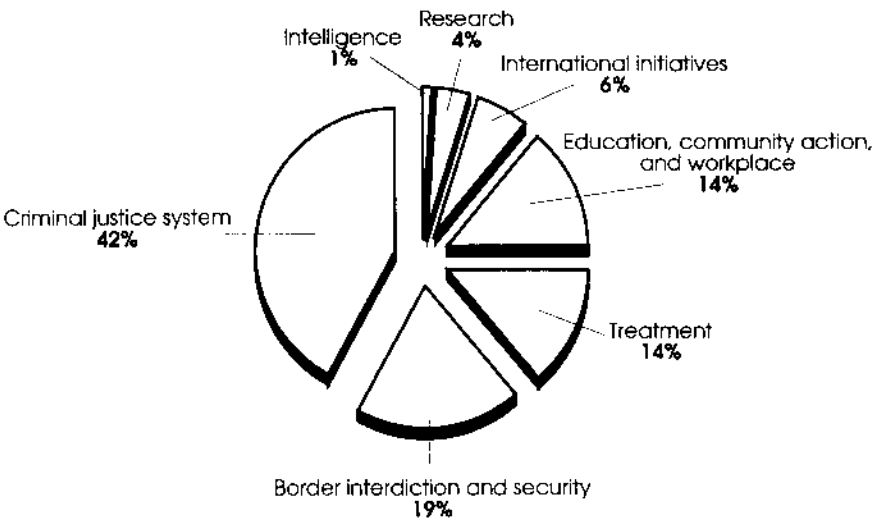
policymakers with respect to this treatment modality. Such a change in attitudes would have a positive effect on both staff of clinics and patients and would undoubtedly lead to appropriate increases in funding. Changes in attitude and enhanced funding would allow more appropriate recruitment of staff, and of even greater importance, the prospective training of potential staff members in each of the disciplines required for excellent treatment programs. These changes of attitude undoubtedly would play an important role in preparing the way for introduction of pharmacotherapeutic interventions or chronic treatments for other addictive diseases. The enormous efforts within the SAMHSA and NIDA administrations to develop new medications would benefit from education of the general public about the rationale and efficacy of methadone maintenance treatment and the need for further research efforts to refine this treatment and to develop new, alternative treatments.

Such a change in the attitudes toward treatment of addiction in general and pharmacotherapy of heroin addiction with methadone maintenance treatment in particular would also help existing treatment staff improve their own self-images and decrease burnout, a significant problem in many clinics now. It would also help improve the self-image of patients and their families. The most tragic occurrences in clinics today happen when patients leave methadone maintenance treatment, to which they have been responding satisfactorily, because of negative attitudes of family members or spouses, only to relapse to injecting heroin use on the street and acquire HIV-1 infection; many later return to methadone maintenance treatment but ultimately succumb to HIV-1 infection and AIDS. These all-too-common occurrences are a human tragedy that can be directly traced to the unfortunate, but widespread, negative attitudes toward treatment.

Finally, essential to progress is fundamental laboratory, clinical, and applied clinical research directly related to methadone maintenance treatment and other treatments and to the biological bases and other factors that may contribute to the acquisition and persistence of the addictions. Only through funding and public and institutional recognition of the importance of such work will we have hopes of offering even more effective prevention efforts, early intervention, and individualized treatment for addictive diseases, including pharmacotherapy and other approaches that prove to be effective in the future.

It is remarkable that even in 1992, with the lay public's voluntary ranking of the substance abuse problem and the AIDS epidemic as major issues of concern in the United States, so few public funds are being expended for treatment, prevention, and research related to substance abuse. A recent GAO report (1992) underscored the fact that with over $11.6 billion to be spent in 1992 for the National Drug Control Strategy, only 32 percent will be spent on demand reduction: 14 percent for treatment, 14 percent for all education, community, and workplace prevention efforts, and less than 4 percent for all basic and applied laboratory and clinical research efforts (see fig. 1).

All the people involved in developing these guidelines should be very proud of the task now completed and should have the hope and expectation that these guidelines will be widely used in a positive way. I think the contributors may also individually feel even more proud of the many years of service they have given to a field that has needed them. I hope that the existence of these guidelines will encourage new workers to commit themselves, attract new talent to this field, and offer societal support to those who



Source: GAO Report *Drug Abuse Research: Federal Funding and Future Needs*. January 1992. Originally published by the Office of National Drug Control Policy.

Figure 1. National Drug Control Budget Authority, FY91

are working in this area of most urgent need.

For Further Reading

Culpepper-Morgan, J.A.; Inturrisi, C.E.; Portenoy, R.K.; Foley, K.; Houde, R.W.; Marsh, F.; and Kreek, M.J. Treatment of opioid induced constipation with oral naloxone. *Clinical Pharmacology and Therapy*, in press.

Des Jarlais, D.C.; Friedman, S.R.; Novick, D.M.; Sotheran, J.L.; Thomas, P.; Yancovitz, S.R.; Mildvan, D.; Weber, J.; Kreek, M.J.; Maslansky, R.; Bartelme, S.; Spira, T.; and Marmor, M. HIV I Infection among intravenous drug users in Manhattan, New York City, 1977 to 1987. *Journal of the American Medical Association* 261:1008–1012, 1989.

Des Jarlais, D.C.; Marmor, M.; Cohen, H.; Yancovitz, S.; Garber, J.; Friedman, S.; Kreek, M.J.; Miescher, A.; Khuri, E.; Friedman, S.M.; Rothenberg, R.; Echenberg, D.; O'Malley, P.O.; Braff, E.; Chin, J.; Burtenol, P.; and Sikes, R.K. Antibodies to a retrovirus etiologically associated with acquired immunodeficiency syndrome (AIDS) in populations with increased incidences of the syndrome. *Morbidity and Mortality Weekly Report* 33:377–379, 1984.

Dole, V.P.; Nyswander, M.E.; and Kreek, M.J. Narcotic blockade: A medical technique for stopping heroin use by addicts. *Transactions of the Association of American Physicians* 79:122–136, 1966.

General Accounting Office. Report to the Chairman, Committee on Government Operations, House of Representatives. In: *Drug Abuse Research: Federal Funding and Future Needs*. GAO/PEMD-92-5, January 1992.

Kennedy, J.A.; Hartman, N.; Sbriglio, R.; Khuri, E.; and Kreek, M.J. Metyrapone-induced withdrawal symptoms. *British Journal of Addictions* 85:1133–1140, 1990.

Kosten, T.R.; Kreek, M.J.; Swift, C.; Carney, M.K.; and Ferdinands, L. Beta-endorphin levels in CSF during methadone maintenance. *Life Sciences* 41:1071–1076, 1987.

Kreek, M.J. Medical safety and side effects of methadone in tolerant individuals. *Journal of the American Medical Association* 223:665–668, 1973*a*.

Kreek, M.J. Plasma and urine levels of methadone. *New York State Journal of Medicine*73:2773–2777, 1973*b*.

Kreek, M.J. Health consequences associated with use of methadone. In: Cooper, J.R.; Altman, F.; Brown, B.S.; and Czechowicz, D., eds. *Research in the Treatment of Narcotic Addiction: State of the Art*. National Institute of Drug Abuse Research Monograph Series.DHHS Pub. No. (ADM)83-1281. Rockville, MD:U.S. Dept. of Health and Human Services, 1983. pp. 456–482.

Kreek, M.J. Multiple drug abuse patterns and medical consequences. In: Meltzer, H.Y., ed. *Psychopharmacology: The Third Generation of Progress*. New York: Raven Press, 1987*a*. pp. 1597–1604.

Kreek, M.J. Tolerance and dependence—Implications for the pharmacological treatment of addiction. In: Harris, L.S., ed. *Problems of Drug Dependence, 1986: Proceedings of the 48th Annual Scientific Meeting of The Committee on Problems of Drug Dependence*. National Institute on Drug Abuse Research Monograph. DHHS Pub. No. (ADM)87–1508. Rockville, MD: U.S. Dept. of Health and Human Services, 1987*b*. pp. 53–61.

Kreek, M.J. Drug interactions in humans related to drug abuse and its treatment. *Modern Methods in Pharmacology* 6:265–282, 1990*a*.

Kreek, M.J. HIV infection and parenteral drug abuse: Ethical issues in diagnosis, treatment, research and the maintenance of confidentiality. In: Allebeck, P., and Jansson, B., eds. *Proceedings of the Third International Congress on Ethics in Medicine—Nobel Conference Series*. New York: Raven Press, 1990*b*. pp. 181–187.

Kreek, M.J. Heroin, other opiates, and the immune function. In: *Drug Abuse and Drug Abuse Research. Third Triennial Report to Congress from the Secretary, Department of Health and Human Services*. DHHS Pub. No. (ADM)91-1704. Rockville, MD: U.S. Dept. of Health and Human Services, 1991*a*.

Kreek, M.J. Using methadone effectively: Achieving goals by application of laboratory, clinical, and evaluation research and by development of innovative programs. In: Pickens, R.; Leukefeld, C.; Schuster, C.R., eds. *Improving Drug Abuse Treatment*. NIDA Research Monograph Series.DHHS Pub. No. (ADM)83–1281.Rockville, MD: U.S. Dept. of Health and Human Services, 1991. pp. 245–266.

Kreek, M.J. Rationale for maintenance pharmacotherapy of opiate dependence. In: O'Brien, C.P., and Jaffe, J.H., eds. *Addictive States*. New York: Raven Press, Ltd., 1992. pp. 205–230.

Kreek, M.J.; Des Jarlais, D.C.; Trepo, C.L.; Novick, D.M.; Abdul-Quader, A.; and Raghunath, J. Contrasting prevalence of delta hepatitis markers in parenteral drug

abusers with and without AIDS. *Journal of Infectious Diseases* 162:538–541, 1990.

Kreek, M.J.; Dodes, L.; Kane, S.; Knobler, J.; and Martin, R. Long-term methadone maintenance therapy: Effects on liver function. *Annals of Internal Medicine* 77:598–602, 1972.

Kreek, M.J.; Raghunath, J.; Plevy, S.; Hamer, D.; Schneider, B.; and Hartman, N. ACTH, Cortisol and beta-endorphin response to metyrapone testing during chronic methadone maintenance treatment in humans. *Neuropeptides* 5:277–278, 1984.

Kreek, M.J.; Wardlaw, S.L.; Friedman, J.; Schneider, B.; and Frantz, A.G. Effects of chronic exogenous opioid administration on levels of one endogenous opioid (beta-endorphin) in man. In: Simon, E., and Takagi, H., eds. *Advances in Endogenous and Exogenous Opioids*. Tokyo, Japan: Kodansha Ltd., 1981. pp. 364–366.

Novick, D.M.; Farci, P.; Karayiannis, P.; Gelb, A.M.; Stenger, R.J.; Kreek, M.J.; and Thomas, H.C. Hepatitis D virus antibody in HBsAg-positive and HBsAg-negative substance abusers with chronic liver disease. *Journal of Medical Virology* 15:351–356, 1985.

Novick, D.M.; Khan, I.; and Kreek, M.J. Acquired immunodeficiency syndrome and infection with hepatitis viruses in individuals abusing drugs by injection. *United Nations Bulletin on Narcotics* 38:15–25, 1986.

Novick, D.M.; Ochshorn, M.; Ghali, V.; Croxson, T.S.; Mercer, W.D.; Chiorazzi, N.; and Kreek, M.J. Natural killer cell activity and lymphocyte subsets in parenteral heroin abusers and long-term methadone maintenance patients. *Journal of Pharmacology and Experimental Therapeutics* 250:606–610, 1989.

Novick, D.M.; Trigg, H.L.; Des Jarlais, D.C.; Friedman, S.R.; Vlahov, D.; and Kreek, M.J. Cocaine injection and ethnicity in parenteral drug users during the early years of the human immunodeficiency virus (HIV) epidemic in New York City. *Journal of Medical Virology* 29:181–185, 1989.

Unterwald, E.M.; Horne-King, J.; and Kreek, M.J. Chronic cocaine alters brain mu opioid receptors. *Brain Research*, in press.

Appendix A—Drugs Used for Treatment of Narcotic Addicts

Part 291

DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Secs.

Authority: Secs. 505, 701 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; Secs. 301(d), 548 of the Public Health Service Act (42 U.S.C. 241(d), 290ee-3); 42 U.S.C. 257a.

§291.501 Methadone in the maintenance treatment of narcotic addicts

(a) The Food and Drug Administration and the Drug Enforcement Administration recognize that the investigational use of methadone requiring the prolonged maintenance of narcotic dependence as part of a total treatment effort has shown promise in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied. It is further felt that additional research is urgently needed so that data may be accumulated which will permit sound determinations of safety, efficacy, and necessary procedural safeguards.

(b) Therefore, the commissioner of Food and Drugs and the Director of the Drug Enforcement Administration Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to conduct further research in this area within a framework of adequate controls designed to protect the individual patients and the community. To facilitate this purpose, the Food and Drug Administration and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable criteria and guidelines which are set forth in §291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

[42 FR 46698, Sept. 16, 1977]

§291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) Definitions. As used in this part:

(1) "Detoxification treatment" means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. There are two types of detoxification treatment: short-term detoxification treatment and long-term detoxification treatment.

(i) "Short-term detoxification treatment" is for a period not in excess of 30 days.

(ii) "Long-term detoxification treatment" is for a period more than 30 days, but not in excess of 180 days.

(2) "Maintenance treatment" means the dispensing of a narcotic drug in the treatment of an individual for dependence on heroin or other morphine-like drug.

(3) A "medical director" is a physician, licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the narcotic treatment program, including ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.

(4) A "medication unit" is a facility established as part of, but geographically dispersed, i.e., separate from a narcotic treatment program from which licensed private practitioners and community pharmacists-

(i) Are permitted to administer and dispense a narcotic drug, and

(ii) Are authorized to collect samples for drug testing or analysis for narcotic drugs.

(5) "Narcotic dependent" means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

(6) A "narcotic treatment program" is an organization (or a person, including a private physician) that administers or dispenses a narcotic drug to a narcotic addict for maintenance or detoxification treatment, provides, when appropriate or necessary, a comprehensive range of medical and rehabilitative services, is approved by the State authority and the Food and Drug Administration, and that is registered with the Drug Enforcement Administration to use a narcotic drug for the treatment of narcotic addiction.

(7) A "program sponsor" is a person (or representative of an organization) who is responsible for the operation of a narcotic treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing services at the program (including its medication units).

(8) The term "services," as used in this part, includes medical evaluations, counseling, rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement, which will help the patient become a productive member of society.

(9) A "State authority" is the agency designated by the Governor or other appropriate official to exercise the responsibility and authority within the State or Territory for governing the treatment of narcotic addiction with a narcotic drug.

(b) Organizational structure and approval requirements-

(1) Organizational structure

(i) A narcotic treatment program may be an independent organization or part of a centralized organization. For example, if a centralized organizational structure consists of a primary facility and other outpatient facilities, all of which conduct initial evaluation of patients and administer or dispense medication, the primary facility and each outpatient facility are separate programs, even though some services (e.g., the same hospital or rehabilitative services) are shared.

(ii) The program sponsor shall submit to the Food and Drug Administration and the State authority a description of the organizational structure of the program, the name of the persons responsible for the program, the address of the program, and the responsibilities of each facility or medication unit. The sources of funding for each program shall be listed and the name and address of each governmental agency providing funding shall be stated.

(iii) Where two or more programs share a central administration (e.g., a city or State-wide organization), the person responsible for the organization (administrator or program sponsor) is required to be listed as the program sponsor for each separate participating program. An individual program shall indicate its participation in the central organization at the time of its application. The administrator or sponsor may fulfill all recordkeeping and reporting requirements for these programs, but each program must continue to receive separate approval.

(iv) One physician may assume primary medical responsibility for more than one program and be listed as medical director. If a physician assumes medical responsibility for more than one program, a statement documenting the feasibility of the arrangement is required to be attached to the application.

(v) [Reserved]

(2) Program approval

(i) Before a narcotic treatment program may be lawfully operated, the program, whether an outpatient facility or a private practitioner, shall submit the applications specified in this section simultaneously to the Food and Drug Administration and the State authority and must receive the approval of both, except as provided for in Paragraph (h)(5) of this section. Before granting approval, the Food and Drug Administration will consult with the Drug Enforcement Administration, Department of Justice, to ascertain if the program is in compliance with Federal controlled substances laws. Each physical location within any program is required to be identified and listed in the approval application. At the time of application for approval, the program sponsor shall indicate whether medication will be administered or dispensed at the facility. Before medication may be administered or dispensed at a location not previously approved for this purpose, the program is required to obtain approval from FDA and the State agency. However, no approval is necessary, but notification is required when a facility in which medication is administered or dispensed is deleted by a program. In that event, the program shall notify the Food and Drug Administration and the State authority within three weeks of the deletion. Similarly, addition or deletion of facilities which provide services other than administering or dispensing medication is also permitted without approval, but notification must be made within 3 weeks to the Food and Drug Administration and the State authority about the addition and/or deletion.

(ii) Exemption of Federal programs. The provisions of this section requiring approval (or permitting disapproval or revocation of approval) by the State authority, compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority do not apply to programs operated directly by the Veterans' Administration or any other department or agency of the United States. Federal agencies operating narcotic treatment programs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal narcotic treatment programs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(iii) Services. Each narcotic treatment program shall provide medical and rehabilitative services and programs. (See Paragraph (d)(4) of this section.) These services should normally be made available at the primary

facility, but the program sponsor may enter into a formal documented agreement with private or public agencies, organizations, or institutions for these services if they are available elsewhere. The program sponsor, in any event, must be able to document that medical and rehabilitative services are fully available to patients.

(iv) Prohibition against unapproved use of narcotic drugs. No prescribing, administering, or dispensing of a narcotic drug for the treatment of narcotic addiction may occur without prior approval by the Food and Drug Administration and the State authority, except as provided for in Paragraph (h)(5) of this section, unless specifically exempted by this section.

(v) Approved narcotic drugs for use in treatment programs. The following narcotic drug has been approved for use in the treatment of narcotic addiction: Methadone.

(3) Medication unit.

(i) A program may establish a medication unit to facilitate the needs of patients who are stabilized on an optimal dosage level. To lawfully operate a medication unit, the program shall, for each separate unit, obtain approval from the Food and Drug Administration, the Drug Enforcement Administration, and the State authority, except as provided for in Paragraph (h)(5) of this section. The Food and Drug Administration, in determining whether to approve a medication unit, will consider the distribution of units within a particular geographic area. Any new medication unit is required to receive approval before it may lawfully commence operation.

(ii) Revocation of approval. If the Food and Drug Administration revokes the primary program's approval, the approval for any medication unit associated with the program is deemed to be automatically revoked. The Food and Drug Administration's revocation of the approval of a particular medication unit, will not, in and of itself, affect the approval of the primary program.

(iii) Narcotic drug supply. A medication unit must receive its supply of the narcotic drug directly from the stocks of the primary facility. Only persons permitted to administer or dispense the drug or security personnel licensed or otherwise authorized by State law to do so may deliver the drug to a medication unit.

(iv) Referral.

(A) The patient shall be stabilized at his or her optimal dosage level before he or she may be referred to a medication unit.

(B) Since the medication unit does not provide a range of services, the program sponsor shall determine that the patient to be referred is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility.

(v) Services. A medication unit is limited to administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs in accordance with Paragraph (d)(2) of this section. If a private practitioner wishes to provide other services besides administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs, he or she must submit an application for separate approval.

(vi) Responsibility for patient. After a patient is referred to a medication unit, the program sponsor retains continuing responsibility for the patient's care. The program sponsor shall ensure that the patient receives needed medical and rehabilitative services at the primary facility.

(c) Conditions for approval of the use of a narcotic drug in a treatment program-

(1) Applicants. An individual listed as program sponsor for a treatment program using a narcotic drug need not personally be a licensed practitioner, but shall employ a licensed physician for the position of medical director. Persons responsible for administering or dispensing the narcotic drug shall be practitioners as defined by Section 102(21) of the Controlled Substances Act (21 U.S.C. 802(21)) and licensed to practice by the State in which the program is to be established.

(2) Assent to regulation.

(i) A person who sponsors a narcotic treatment program, and any persons responsible for a particular program, shall agree to adhere to all the rules, directives, and procedures, set forth in this section, and any regulation regarding the use of narcotic drugs in the treatment of narcotic addiction which may be promulgated in the future. The program sponsor has responsibility for all personnel and individuals providing services, who work in the program at the primary facility or at other facilities or medication units. The program sponsors shall agree to inform all personnel

and individuals providing services of the provisions of this section and to monitor their activities to assure compliance with the provisions.

(ii) The Food and Drug Administration and the State authority are required to be notified within 3 weeks of any replacement of the program sponsor or medical director. Activities in violation of this regulation may give rise to the sanctions set forth in paragraph (i) of this section.

(3) Description of facilities. Only program site(s) approved by Federal, State, and local authorities may treat narcotic addicts with a narcotic drug. To obtain program approval, the applicant shall demonstrate that he or she will have access to adequate physical facilities to provide all necessary services. A program must have ready access to a comprehensive range of medical and rehabilitative services so that the services may be provided when necessary. The name, address and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services are required to be included in the application submitted to the Food and Drug Administration and the State authority. The application is also required to include the name and address of each medication unit.

(4) Submission of proper applications. The following applications shall be filed simultaneously with both the Food and Drug Administration and the State authority.

(i) Form FDA-2632 "Application for Approval of Use of Methadone in a Treatment Program." This form, required by Paragraph (k) of this section, shall be completed and signed by the program sponsor and submitted in duplicate to the Food and Drug Administration and the State authority.

(ii) Form FDA-2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program." This form required by Paragraph (k) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense narcotic drugs and submitted in duplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed even if they are not responsible for administering or dispensing the drug at the time the application is submitted.

(5) State and Federal approval, denial, and revocation of approval of narcotic treatment programs.

(i) The Food and Drug Administration may grant approval to a program only after FDA has received notification from both the State authority and the Drug Enforcement Administration that the program conforms to all pertinent State and Federal requirements.

(ii) The Food and Drug Administration will revoke the approval of a narcotic treatment program if so requested by the State authority or the Drug Enforcement Administration. If approval of a program is denied or revoked, the program shall have a right to appeal to the Commissioner, as provided for in Paragraph (h)(5) of this section.

(iii) No shipment of a narcotic drug may lawfully be made to any program which does not have current approval from the Food and Drug Administration. Within 60 days after receipt of the application from the program sponsor for approval, the Food and Drug Administration will notify the sponsor whether the application is approved or denied.

(d)(1) Minimum standards for admission-

(i) History of addiction and current physiologic dependence.

(A) A person may be admitted as a patient for a maintenance program only if a program physician determines that the person is currently physiologically dependent upon a narcotic drug and became physiologically dependent at least 1 year before admission for maintenance treatment. A 1-year history of addiction means that an applicant for admission to a maintenance program was physiologically addicted to a narcotic at a time at least 1 year before admission to a program and was addicted, continuously or episodically, for most of the year immediately before admission to a program. In the case of a person for whom the exact date on which physiological addiction began cannot be ascertained, the admitting program physician may, in his or her reasonable clinical judgment, admit the person to maintenance treatment, if from the evidence presented, observed, and recorded in the patient's record, it is reasonable to conclude that there was physiologic dependence at a time approximately 1 year before admission.

(B) Although daily use of a narcotic for an entire year could satisfy the regulatory definition of a 1-year history of addiction, operationally one might be physiologically dependent without daily use during the entire 1-year period and still satisfy the definition. The following, although not exhaustive, are examples of applicants who would

meet the minimum standard of a 1-year history of addiction and who, if currently physiologically dependent on the date of application for admission, would be eligible for admission to a maintenance program:

(1) Physiologic addiction began in August 1987 and continued to the date of application for admission in August 1988.

(2) Physiologic addiction began in January 1988 and continued until April 1988. Physiologic addiction began again in July 1988 and continued until the application for admission in January 1989.

(3) Physiologic addiction began in January 1987 and continued until October 1987. The date of application for admission was January 1988, at which time the patient had been readdicted for 1 month preceding his or her admission.

(4) Physiologic addiction consisted of four episodes in the last year, each episode lasting 2½ months.

(C) The program physician or an appropriately trained staff member designated and supervised by the physician shall record in the patient's record the criteria used to determine the patient's current physiologic dependence and history of addiction. In the latter circumstances, the program physician shall review, date, and countersign the supervised staff member's evaluation to demonstrate his or her agreement with the evaluation. The program physician shall make the final determination concerning a patient's physiologic dependence and history of addiction. The program physician shall sign, date, and record a statement that he or she has reviewed all the documented evidence to support a 1-year history of addiction and the current physiologic dependence and that in his or her reasonable clinical judgment the patient fulfills the requirements for admission to maintenance treatment. The program physician shall complete and record the statement before the program administers any methadone to the patient.

(ii) Voluntary participation, informed consent. The person responsible for the program shall ensure that: A patient voluntarily chooses to participate in a program; all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the "Consent to Methadone Treatment" Form FDA-2635 (see Paragraph (k) of this section); a parent, legal guardian, or responsible adult designated by the State authority (e.g., "emancipated minor" laws) sign for patients under the age of 18 the second part of Form FDA-2635 "Consent to Methadone Treatment."

(iii) Exceptions to minimum admission criteria-

(A) Penal or chronic care. A person who has resided in a penal or chronic care institution for 1 month or longer may be admitted to maintenance treatment within 14 days before release or discharge, or within 6 months after release from such an institution without documented evidence to support findings of physiological dependence, provided the person would have been eligible for admission before he or she was incarcerated or institutionalized and, in the reasonable clinical judgment of a program physician, treatment is medically justified. Documented evidence of the prior residence in a penal or chronic care institution and evidence of all other findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(B) Pregnant patients.

(1) Pregnant patients, regardless of age, who have had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a maintenance regimen. For such patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, in his or her reasonable clinical judgment, finds treatment to be medically justified. Evidence of all findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial methadone dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial methadone dose to the patient. Pregnant patients are required to be given the opportunity for prenatal care either by the program or by referral to appropriate health-care providers.

(2) If a program cannot provide direct prenatal care for pregnant patients in treatment, the program shall establish a system for informing the patients of the publicly or privately funded prenatal care opportunities available. If there are no publicly funded prenatal referral opportunities and the program cannot provide such services or the patient cannot afford them or refuses them, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as part of its counseling service.

(3) Counseling records and/or other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the patient is referred for prenatal services, the physician to whom she is referred is required to be notified that she is in maintenance treatment, provided that notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If a pregnant patient refuses direct treatment or appropriate referral for treatment, the treating program physician should consider using informed consent procedures; e.g., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it. The program physician, consistent with the confidentiality regulations, shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. If the program physician does not receive a response to the request, he or she shall document in the record that such a request was made.

(4) Within 3 months after termination of pregnancy, the program physician shall enter an evaluation of the patient's treatment state into her record and state whether she should remain in the maintenance program or be detoxified.

(5) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if treatment is deemed necessary. The program sponsor shall ensure that each female patient is fully informed of the possible risks to her or to her unborn child from continued use of illicit drugs and from the use of or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) Previously treated patients. Under certain circumstances, a patient who has been treated and later voluntarily detoxified from maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the program attended is able to document prior narcotic drug maintenance treatment of 6 months or more, and the admitting program physician, in his or her reasonable clinical judgment, finds readmission to maintenance treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. The admitting program physician or a program employee under supervision of the admitting program physician must enter in the patient's record documented evidence of the patient's prior treatment and evidence of all decisions and criteria used relating to the admission of the patient and the quantity of take-home medication permitted. The admitting program physician shall date and sign these entries in the patient's record or review the health-care professional's entries therein before the program administers any medication to the patient. In the latter case, the admitting program physician shall date and sign the entries in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(iv) Special limitation; treatment of patients under 18 years of age. A person under 18 is required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. A 1-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian or responsible adult designated by the State authority (e.g., "emancipated minor" laws) completes and signs consent form, Form FDA-2635 "Consent to Methadone Treatment."

(v) Denial of admission. If in the reasonable clinical judgment of the medical director a particular patient would not benefit from treatment with a narcotic drug, the patient may be refused such treatment even if the patient meets the admission standards.

(2) Minimum testing or analysis for drugs: Uses and frequency.

(i) The person(s) responsible for a program shall ensure that: An initial drug-screening test or analysis is completed for each prospective patient; at least eight additional random tests or analyses are performed on each patient during the first year in maintenance treatment; and at least quarterly random tests or analyses are performed on

each patient in maintenance treatment for each subsequent year, except that a random test or analysis is performed monthly on each patient who receives a 6-day supply of take-home medication. When a sample is collected from each patient for such test or analysis, it must be done in a manner that minimizes opportunity for falsification. Each test or analysis must be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this regulation shall be in compliance with all applicable Federal proficiency testing and licensing standards and all applicable State standards. If a program proposes to change a laboratory used for such testing or analysis, the program shall have the change approved by the Food and Drug Administration.

(ii) The person responsible for a program shall ensure that test results are not used as the sole criterion to force a patient out of treatment but are used as a guide to change treatment approaches. The person responsible for a program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

(3) Patient evaluation; minimum admission and periodic requirements-

(i) Minimum contents of medical evaluation. Each patient is required to have a medical evaluation by a program physician or an authorized health-care professional under the supervision of a program physician on admission to a program. At a minimum, this evaluation is required to consist of a medical history which includes the required history of narcotic dependence, evidence of current physiologic dependence unless excepted by the regulations, and a physical examination, and includes the following laboratory examinations: serological test for syphilis, a tuberculin skin test, and a test or analysis for drug determination. If in the reasonable clinical judgment of the program physician, a patient's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained, the serological test for syphilis may be omitted. The physical examination is required to consist of an investigation of the organ systems for possibilities of infectious disease, pulmonary, liver, and cardiac abnormalities, and dermatologic sequelae of addiction. In addition, the physical examination is required to include a determination of the patient's vital signs (temperature, pulse, and blood pressure and respiratory rate); an examination of the patient's general appearance, head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment; and the program physician's overall impression of the patient.

(ii) Recordings of findings. The admitting program physician or an appropriately trained health care professional supervised by the admitting program physician shall record in the patient's record all findings from the admission medical evaluation. In each case, the admitting program physician shall date and sign these entries, or date, review, and countersign these recordings in the patient's record to signify his or her review of and concurrence with the history and physical findings.

(iii) Admission evaluation.

(A) Each patient seeking admission or readmission for treatment services is required to be interviewed by a well-trained program counselor, qualified by virtue of education, training, or experience to assess the psychological and sociological background of drug abusers, to determine the appropriate treatment plan for the patient. To determine the most appropriate treatment plan for a patient, the interviewer shall obtain and document in the patient's record the patient's history.

(B) A patient's history includes information relating to his or her educational and vocational achievements. If a patient has no such history; i.e., he or she has no formal education or has never had an occupation, this requirement is met by writing this information in the patient's history.

(iv) Initial treatment plan.

(A)(1) The initial treatment plan is required to contain a statement that outlines realistic short-term treatment goals which are mutually acceptable to the patient and the program. The initial treatment plan is also required to spell out the behavioral tasks a patient must perform to complete each short-term goal; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The plan is also required to identify the frequency with which these services are likely to be provided. Prior to developing a treatment plan, the patient's needs for medical, social, and psychological services; education; vocational rehabilitation; and employment must be assessed, and the needs reflected, when clinically appropriate, in the treatment plan.

(2) A primary counselor is one who is assigned by the program to develop, implement, and evaluate the patient's initial and periodic treatment plan and to monitor a patient's progress in treatment. The primary counselor shall enter in the patient's record the counselor's name, the contents of a patient's initial assessment, and the initial treatment plan. The primary counselor shall make these entries immediately after the patient is stabilized on a dose or within 4 weeks after admission, whichever is sooner.

(B) It is recognized that patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables; e.g., patient resources, available program, and community services. It is not the intent of this regulation to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

(C) The program supervisory counselor or other appropriate program personnel so designated by the program physician shall review and countersign all the information and findings required to be recorded in each patient's record under Paragraph (d)(3)(iv) of this section.

(v) Periodic treatment plan evaluation.

(A) The program physician or the primary counselor shall review, reevaluate, and alter where necessary each patient's treatment plan at least once each 90 days during the first year of treatment, and then at least twice a year after the first year of continuous treatment.

(B) The program physician shall ensure that the periodic treatment plan becomes part of each patient's record and that it is signed and dated in the patient's record by the primary counselor and is countersigned and dated by the supervisory counselor.

(C) At least once a year, the program physician shall date, review, and countersign the treatment plan recorded in each patient's record and ensure that each patient's progress or lack of progress in achieving the treatment goals is entered in the patient's record by the primary counselor. When appropriate, the treatment plan and progress notes should deal with the patient's mental and physical problems, apart from drug abuse. The treatment plan is required to include the name of and the reasons for prescribing any medication for emotional or physical problems.

(D) The requirement for annual physician review and signature by the program physician in Paragraph (d)(3)(v)(C) of this section is discretionary, however, as it applies to a patient, who has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the maintenance treatment program and who has made substantial progress in rehabilitation.

(4) Minimum program services-

(i)(A) Access to a range of services. A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients, especially during the first 3 years of treatment.

(B) Pregnant patients

(1) For pregnant patients in a treatment program who were not admitted under Paragraph (d)(1)(iii)(B) of this section, a treatment program shall give them the opportunity for prenatal care either by the narcotic treatment program or by referral to appropriate health care providers. If a program cannot provide direct prenatal care for pregnant patients in treatment, it shall establish a system of referring them for prenatal care which may be either publicly or privately funded. If there is no publicly funded prenatal care available to which a patient may be referred, and the program cannot provide such services, or the patient cannot afford or refuses prenatal care services, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.

(2) Counseling records and other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the program refers a patient for prenatal services, it shall inform the physician to whom she is referred that the patient is in maintenance treatment, provided such notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures; i.e., to have the patient acknowledge in writing that she has the opportunity for this treatment but refuses it. The program physician shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. The information should be obtained in accordance with the Department of Health and Human

Services' confidentiality regulations (42 CFR Part 2). If no response is received, the program physician shall document in the record that such a request was made and no response was received.

(3) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued treatment is deemed necessary. It is the responsibility of the program sponsor to ensure that each female patient is fully informed of the possible risks to a pregnant woman and her unborn child from continued use of illicit drugs and from the use of, or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) [Reserved]

(D) Off-site services. Any service not furnished at the primary facility is required to be listed in any application for approval submitted to the Food and Drug Administration or to the State authority. The addition, modification, or deletion of any program service is required to be reported immediately to the Food and Drug Administration.

(ii) Minimum medical services; designation of medical director and responsibilities. Each program shall have a designated medical director who assumes responsibility for administering all medical services performed by the program. The medical director and other authorized program physicians are required to be licensed to practice medicine in the jurisdiction in which the program is located. The medical director is responsible for ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding medical treatment of narcotic addiction. In addition, the medical director or other authorized physicians shall:

(A) Ensure that evidence of current physiologic dependence, length of history of addiction, or exceptions to criteria for admission are documented in the patient's record before the patient receives the initial dose.

(B) Ensure that a medical evaluation, including a medical history has been taken, and physical examination has been done before the patient receives the initial dose (except that in an emergency situation, the initial dose may be given before the physical examination).

(C) Ensure that appropriate laboratory studies have been performed and reviewed.

(D) Sign or countersign all medical orders as required by Federal or State law. (Such medical orders include but are not limited to the initial medication orders and all subsequent medication order changes, all changes in the frequency of take-home medication and prescribing additional take-home medication for an emergency situation.)

(E) Review and countersign treatment plans at least annually as qualified by Paragraph (d)(3)(v)(D) of this section.

(F) Ensure that justification is recorded in the patient's record for reducing the frequency of clinic visits for observed drug ingesting, providing additional take-home medication under exceptional circumstances or when there is physical disability, or prescribing any medication for physical or emotional problems.

(iii) Use of health-care professionals. Although the final decision to accept a patient for treatment may be made only by the medical director or other designated program physician, it is recognized that physicians can train program personnel to detect and document narcotic abstinence symptoms and that some jurisdictions allow State-licensed or certified health-care professionals; e.g., physician's assistants, nurse practitioners, to perform certain functions — record medical histories, perform physical examinations, and prescribe, administer, or dispense certain medications — that are ordinarily performed by a licensed physician. These regulations do not prohibit licensed or certified health-care professionals from performing those functions in narcotic treatment programs if it is authorized by Federal, State, and local laws and regulations, and if those functions are delegated to them by the medical director, and records are properly countersigned by the medical director or a licensed physician.

(iv) Vocational rehabilitation, education, and employment. Each program shall provide opportunities directly, or through referral to community resources, for patients who either desire or have been deemed by the program staff to be ready to participate in educational job training programs or to obtain gainful employment as soon as possible.

(5) Staffing patterns-

(i) Program personnel. The person(s) responsible for a program shall determine program personnel requirements after considering the number of patients who are vocationally and educationally impaired; the number of patients with significant psychopathology; the number of patients who are also non-narcotic drug or alcohol

abusers; the number of patients with behavioral problems in the program; and the number of patients with serious medical problems.

(ii) Supportive services. The person(s) responsible for the program shall take notice, when considering the staffing pattern, that maintenance treatment programs need to establish supportive services in accordance with the varying characteristics and needs of their patient populations. The person(s) responsible for a program shall also take notice of the availability of existing community resources which may complement or enhance the program's delivery of supportive services and then establish a staffing pattern based on a combination of patient needs and available, accessible community resources.

(6) Frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization-

(i) Dosage and responsibility for administration.

(A) The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 milligrams and that the total dose for the first day does not exceed 40 milligrams, unless the program medical director documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(B) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each patient's record each change in dosage schedule.

(C) The administering licensed physician shall ensure that a daily dose greater than 100 milligrams is justified in the patient's record.

(ii) Authorized dispensers of narcotic drugs; responsibility. A narcotic drug may be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health-care professional authorized by Federal and State law to administer or dispense narcotic drugs. The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

(iii) Form. Methadone may be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form when the attending physician judges it advisable. Although tablet, syrup concentrate, or other formulations may be distributed to the program, all oral medication is required to be administered or dispensed in a liquid formulation. The oral dosage form is required to be formulated in such a way as to reduce its potential for parenteral abuse. Take-home medication is required to be labeled with the treatment center's name, address, and telephone number and must be packaged in special packaging as required by 16 CFR 1700.14 in accordance with the Poison Prevention Packaging Act (Pub. L. 91-601, 15 U.S.C. 1471 et seq.) to reduce the chances of accidental ingestion. Exceptions may be granted when these provisions conflict with State law with regard to the administering or dispensing of drugs.

(iv) Take-home medication

(A) Take-home medication may be given only to a patient who, in the reasonable clinical judgment of the program physician, is responsible in handling narcotic drugs. Before the program physician reduces the frequency of a patient's clinical visits, she or he or a designated staff member shall record the rationale for the decision in the patient's clinical record. If this is done by a designated staff member, a program physician shall review, countersign, and date the patient's record where this information is recorded.

(B) The program physician shall consider the following in determining whether, in his or her reasonable clinical judgment, a patient is responsible in handling narcotic drugs:

(1) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol;

(2) Regularity of clinic attendance;

(3) Absence of serious behavioral problems at the clinic;

(4) Absence of known recent criminal activity, e.g., drug dealing;

(5) Stability of the patient's home environment and social relationships;

(6) Length of time in maintenance treatment;

(7) Assurance that take-home medication can be safely stored within the patient's home; and

(8) Whether the rehabilitative benefit to the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(v) Take-home requirements. The requirement of time in treatment is a minimum reference point after which a patient may be eligible for take-home privileges. The time reference is not intended to mean that a patient in treatment for a particular time has a specific right to take-home medication. Thus, regardless of time in treatment, a program physician may, in his or her reasonable judgment, deny or rescind the take-home medication privileges of a patient.

(A)(1) In maintenance treatment, it is required that a patient come to the clinic for observation daily or at least 6 days a week. If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 months, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section, and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her attendance at the clinic for observation to three times weekly. The patient may receive no more than a 2-day take-home supply of medication.

(2) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 2 years from his or her entrance into the program, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her clinic attendance at the clinic for observation to twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication.

(3) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the maintenance treatment program, has made substantial progress in rehabilitation, has no major behavioral problems, is responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of his or her clinic attendance for observation, the patient may be permitted to reduce clinic attendance for observation to once weekly, provided that the following additional criteria are met:

The program physician has written into the patient's record an evaluation that the patient is responsible in handling narcotic drugs (Paragraphs (d)(6)(iv)(B) (1) through (8) of this section); the patient is employed (or actively seeking employment), attends school, is a homemaker, or is considered unemployable for mental or physical reasons by a program physician; the patient is not known to have abused drugs, including alcohol in the last year; and the patient is not known to have engaged in criminal activity; e.g., drug dealing in the last year. A patient is permitted to reduce clinic attendance for observation to once weekly may receive no more than a 6-day take-home supply of medication.

(B)(1) If a patient, after receiving a supply of take-home medication, is inexcusably absent from or misses a scheduled appointment with a treatment program without authorization from the program staff, the program physician shall increase the frequency of the patient's clinic attendance for drug ingestion under observation. For such a patient, the program physician shall not reduce the frequency of the patient's clinic attendance for drug ingestion under observation until she or he has had at least three consecutive monthly tests or analyses that are neither positive for morphine-like drugs (except from the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and until she or he is again determined by a program physician to be responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section) and to meet criteria in Paragraph (d)(6)(v)(A) of this section.

(2) If a patient, after receiving a 6-day supply of take-home medication, has a test or analysis which is confirmed to be positive for morphine-like drugs (except for the narcotic drug administered or dispensed by

the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall place the patient on probation for 3 months. If, during this probation, the patient has a test or analysis either positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall increase the frequency of the patient's clinic attendance for observation to at least twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication until she or he has had at least three consecutive monthly tests or analyses which are neither positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and the program physician again determines that the patient is responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section) and meets the criteria contained in Paragraph (d)(6)(v)(A) of this section.

(C) In calculating the number of years of maintenance treatment, the period is considered to begin on the first day the medication is administered, or on readmission if a patient has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program is counted toward the number of years of treatment, provided there has not been a continuous absence of 90 days or more.

(D) Each patient whose daily dose is above 100 milligrams is required to be under observation while ingesting the drug at least 6 days per week irrespective of the length of time in treatment, unless the program has received prior approval from the Food and Drug Administration with the concurrence of the State authority.

(vi) Exceptions to take-home requirements. If, in the reasonable clinical judgment of the program physician:

(A) A patient is found to have a physical disability which interferes with his or her ability to conform to the applicable mandatory schedule, she or he may be permitted a temporarily or permanently reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs.

(B) A patient, because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, is unable to conform to the applicable mandatory schedule, she or he may be permitted a temporarily reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs. The rationale for an exception to a mandatory schedule is to be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's record by the program physician or by program personnel supervised by the program physician. In the latter situation, the physician shall review, countersign, and date the patient's record where this rationale is recorded. In any event, a patient may not be given more than a 2 week supply of narcotic drugs at one time.

(vii) Official State holidays. If a treatment center program is not in operation due to the observance of an official State holiday, patients may be permitted one extra take-home dose per visit and one fewer clinic visit per week to allow patients not to have to attend the clinic on an official State holiday. An official State holiday is a holiday on which most State offices are usually closed and routine State government business is not conducted.

(7) [Reserved]

(8) Minimum standards for short-term detoxification treatment.

(i) For short-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered daily, under close observation, in reducing dosages over a period not to exceed 30 days. All requirements for maintenance treatment apply to short-term detoxification treatment with the following exceptions:

(A) Take-home medication is not allowed during short-term detoxification.

(B) A history of 1 year physiologic dependence is not required for admission to short-term detoxification.

(C) Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be placed in short-term detoxification treatment, regardless of age.

(D) No test or analysis is required except for the initial drug screening test or analysis.

(E) The initial treatment plan and periodic treatment plan evaluation required for maintenance patients are not necessary for short-term detoxification patients. However, a primary counselor must be assigned by the program to monitor a patient's progress toward the goal of short-term detoxification and possible drug-free treatment referral.

(F) The requirements of Paragraph (d)(4) of this section, except Paragraphs (d)(4)(ii) (A) through (D) and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

(ii) A patient is required to wait at least 7 days between concluding a short-term detoxification treatment episode and beginning another. Before a short-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be, or is again, physiologically dependent on narcotic drugs. The provisions of these requirements, except as noted in Paragraph (d)(8)(i) of this section, apply to both inpatient and ambulatory short-term detoxification treatment.

(iii) Short-term detoxification treatment is not recommended for a pregnant patient.

(9) Minimum standards for long-term detoxification treatment.

(i) For long-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered on a regimen designed to reach a drug-free state and to make progress in rehabilitation in 180 days or less. All requirements for maintenance treatment apply to long-term detoxification treatment with the following exception.

(A) In long-term detoxification treatment, it is required that the patient be under observation while ingesting the drug daily or at least 6 days a week, for the duration of the long-term detoxification treatment.

(B) A history of 1 year physiologic dependence is not required for admission to long-term detoxification.

(C) The program physician shall document in the patient's record that short-term detoxification is not a sufficiently long enough treatment course to provide the patient with the additional program services he or she deems necessary for the patient's rehabilitation. The program physician shall document this information in the patient's record before long-term detoxification may begin.

(D) Patients who have been determined by the program physician to be currently physiologically dependent on narcotics may be placed in long-term detoxification treatment, regardless of age.

(E) An initial drug screening test or analysis is required for each patient. And at least one additional random test or analysis must be performed monthly on each patient during long-term detoxification.

(F) The initial treatment plan and periodic treatment plan evaluation required for maintenance patients are also required for long-term detoxification patients, except that the required periodic treatment plan evaluation is required to occur monthly.

(ii) A patient is required to wait at least 7 days between concluding a long-term treatment episode and beginning another. Before a long-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. The provisions of these requirements apply to both inpatient and ambulatory long-term detoxification treatment.

(iii) Long-term detoxification is not recommended for a pregnant patient.

(10) Inspections of programs; patient confidentiality. A program shall allow inspections by duly authorized employees of the State authority, and in accordance with Federal controlled substances law and Federal confidentiality laws, by duly authorized employees of the Food and Drug Administration, the Drug Enforcement Administration of the Department of Justice, and the National Institute on Drug Abuse.

(11) Exemptions from specific program standards.

(i) A program is permitted, at the time of application or any time thereafter, to request exemption from specific program standards. The rationale for an exemption shall be thoroughly documented in an appendix to be submitted with the application or at some later time. The Food and Drug Administration will approve such exemptions of program standards at the time of application, or any time thereafter, with the concurrence of the State authority. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a nonmetropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards.

(ii) The Food and Drug Administration has the right to withhold the granting of an exemption requested at the time of application until a program is in actual operation in order to assess if the exemption is necessary. If periodic inspections of the program reveal that discrepancies or adverse conditions exist, the Food and Drug Administration shall reserve the right to revoke any or all exemptions previously granted.

(12) Research. When a program conducts research on human subjects or provides subjects for research, there must be written policies and written review to assure the rights of the patients involved. Appropriate informed consent forms are required to be signed by the patient and to be retained in his or her patient record at the program. All research, development, and related activities which involve human subjects and which are funded by grants from or contracts with the Department of Health and Human Services are required to comply with the Department of Health and Human Services' regulations on the protection of human subjects, 45 CFR Part 46, and confidentiality of information, 42 CFR Part 2. All investigational research involving human subjects conducted for submission to the Food and Drug Administration must be conducted in compliance with Part 312 of this chapter.

(13) Patient record system-

(i) Patient care. The person(s) responsible for a program shall establish a record system to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to methadone. All records are required to be kept confidential and in accordance with all applicable Federal and State regulations regarding confidentiality.

(ii) Drug dispensing. The person(s) responsible for a program shall ensure that accurate records traceable to specific patients are maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records must be retained for a period of 3 years from the date of dispensing.

(iii) Patient's record. An adequate record must be maintained for each patient. The record is required to contain a copy of the signed consent form(s), the date of each visit, the amount of drug administered or dispensed, the results of each test or analysis for drugs, any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and is to be so noted in the patient's record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and is to be so noted in the patient's record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of narcotic drugs (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress must be entered in the patient's record.

(14) Security of drug stocks. Adequate security is required to be maintained over drug stocks, over the manner in which it is administered or dispensed, over the manner in which it is distributed to medication units, and over the manner in which it is stored to guard against theft and diversion of the drug. The program is required to meet the security standards for the distribution and storage of controlled substances as required by the Drug Enforcement Administration, Department of Justice (21 CFR 1301.72-1301.76).

(e) Multiple enrollments-

(1) Administering or dispensing to patients enrolled in other programs. There is a danger of drug dependent persons attempting to enroll in more than one narcotic treatment program to obtain quantities of drugs for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, drugs shall not be provided to a patient who is known to be currently receiving drugs from another treatment program.

(2) Patient attendance requirements. The patient shall always report to the same treatment facility unless prior approval is obtained from the program sponsor for treatment at another program. Permission to

report for treatment at the facility of another program shall be granted only in exceptional circumstances and shall be noted on the patient's clinical record.

(f) Conditions for use of narcotic drugs in hospitals for detoxification treatment-

(1) Form. The drug may be administered or dispensed in either oral or parenteral form. (See Paragraph (d)(6)(iii) of this section.)

(2) Use of narcotic drugs in hospitals-

(1) Approved uses. For hospitalized patients, the use of a narcotic drug for narcotic addict treatment may be administered or dispensed only for detoxification treatment. If a narcotic drug is administered for treatment of narcotic dependence for more than 180 days, the procedure is no longer considered detoxification but is, rather, considered maintenance treatment. Only approved narcotic treatment programs may undertake maintenance treatment. This does not preclude the maintenance treatment of a patient who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his or her stay or whose enrollment in a program which has approval for maintenance treatment using narcotic drugs has been verified. (See 21 CFR 1306.07(c).) Any hospital which already has received approval under this paragraph (f) may serve as a temporary narcotic treatment program when an approved treatment program has been terminated, and there is no other facility immediately available in the area to provide narcotic drug treatment for the patients. The Food and Drug Administration may give this approval upon the request of the State authority or the hospital, when no State authority has been established.

(ii) [sic] Individuals responsible for supplies. Hospitals shall submit to the Food and Drug Administration and the State authority the name of the individual (e.g., pharmacist) responsible for receiving and securing supplies of narcotic drugs for the treatment of narcotic addicts. The individual responsible for supplies shall ensure that the only persons who receive supplies of narcotic drugs are those who are authorized to do so by Federal or State law.

(iii) General description. The hospital shall submit to the Food and Drug Administration and the State authority a general description of the hospital, including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken.

(iv) Anticipated quantity of drug needed. The hospital shall submit to the Food and Drug Administration and the State authority the anticipated quantity of narcotic drugs for narcotic addict treatment needed per year.

(v) Records. The hospital shall maintain accurate records showing dates, quantity, and batch or code marks of the drug used for inpatient treatment. The hospital shall retain the records for at least a period of 3 years.

(vi) Inspection. The hospital shall permit the Food and Drug Administration and the State authority to inspect supplies of the drug at the hospital and evaluate the uses to which the drug is being put. The Food and Drug Administration and the State authority will keep the identity of the patients confidential in accordance with confidentiality requirements of 42 CFR Part 2. Records on the receipt, storage, and distribution of narcotic medication are subject to inspection under Federal controlled substances law; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(vii) Approval of hospital pharmacy. Application for a hospital pharmacy to provide narcotic drugs for detoxification treatment must be submitted to the Food and Drug Administration and the State authority and approval from both is required, except as provided for in Paragraph (h)(5) of this section. Within 60 days after the Food and Drug Administration receives the application, it will notify the applicant of approval or denial or will request additional information, when necessary.

(viii) Approval of shipments to hospital pharmacies. Before a hospital pharmacy may lawfully receive shipments of narcotic drugs for detoxification treatment, a responsible official shall complete, sign, and file in duplicate with the Food and Drug Administration and the State authority Form FDA-2636 "Hospital Request for Methadone Detoxification Treatment" (see Paragraph (k) of this section) and must have received from the Food and Drug Administration a notice that the request has been approved.

(ix) Sanctions. Failure to abide by the requirements described in this section may result in revocation of approval to receive shipments of narcotic drugs for narcotic addict treatment, seizure of the drug supply on hand, injunction, and criminal prosecution.

(g) Confidentiality of patient records.

(1) Except as provided in Paragraph (g)(2) of this section, disclosure of patient records maintained by any program is governed by the provisions of 42 CFR Part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of narcotic medication are also subject to inspection under Federal controlled substances laws: But use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(2) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Food and Drug Administration to have access to and to copy all records on the use of narcotic drugs in accordance with the provisions of 42 CFR Part 2. A treatment program may reveal such records only when necessary in a related administrative or court proceeding.

(h) Denial or revocation of approval.

(1) Complete or partial denial or revocation of approval of an application to receive shipments of narcotic drugs (Forms FDA-2632 "Application for Approval of Use of Methadone in a Treatment Program" and FDA-2636 "Hospital Request for Methadone Detoxification Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Center for Drug Evaluation and Research, on his or her own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Drug Abuse, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Commissioner, the Director of the Center for Drug Evaluation and Research, or his or her representative, will notify the applicant in writing of the proposed action and the reasons therefor and will offer the applicant an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Center for Drug Evaluation and Research as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the Commissioner will evaluate information obtained in the informal conference and/or in writing before the Director of the Center for Drug Evaluation and Research. If the Commissioner finds that the applicant has failed to submit adequate assurance justifying approval of the application, the Commissioner shall issue a notice of opportunity for hearing with respect to the matter pursuant to §314.200 of this chapter and the matter shall thereafter be handled in accordance with established procedures for denial or revocation of approval of a new drug application. If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedure will be expedited. Upon revocation of approval of an application, the Commissioner will notify the applicant, the State authority, the Drug Enforcement Administration, Department of Justice, and all other appropriate persons that the applicant may no longer receive shipments of narcotic drugs, and will require the recall of all of the drugs from the applicant. Revocation of approval may also result in criminal prosecution.

(4) Denial or revocation of approval may be reversed when the Commissioner determines that the applicant has justified approval of the application.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Center for Drug Evaluation and Research, who shall hold an informal conference on the matter in accordance with Paragraph (h)(2) of this section. The State authority may participate in the conference. The appellant or the State authority may appeal the Director's decision to the Commissioner, who shall decide the matter in accordance with Paragraph (h)(3) of this section. If the Commissioner denies or revokes approval, such action shall be handled in accordance with Paragraph (h)(3) of this section. The Commissioner may not grant or retain Food and Drug Administration approval if the Commissioner finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(i) Sanctions-

(1) Program sponsor or individual responsible for a particular program. If the program sponsor or the person responsible for a particular program fails to abide by all the requirements set forth in this regulation, or fails to adequately monitor the activities of those employed in the program, he or she may have the approval of his or her application revoked, his or her narcotic drug supply seized, an injunction granted precluding operation of his or her program, and criminal prosecution instituted against him or her.

(2) Persons responsible for administering or dispensing narcotic drugs. If a person responsible for administering or dispensing narcotic drugs for narcotic addict treatment fails to abide by all the requirements set forth in this regulation, criminal prosecution may be instituted against him or her, his or her drug supply may be seized, the approval of the program may be revoked, and an injunction may be granted precluding operation of the program.

(j) Requirements for distribution by manufacturers of narcotic drugs for narcotic addict treatment-

(1) Distribution requirements. Shipments of narcotic drugs for narcotic addict treatment are restricted to direct shipments by manufacturers of the drugs to approved treatment programs using the narcotic drugs and to approved hospital pharmacies. If requested by a manufacturer or State authority, wholesale pharmacy outlets in some regions or States may be authorized to stock narcotic drugs for narcotic addict treatment for that area and then transship the drug to approved narcotic treatment programs and approved hospital pharmacies. Alternative methods of distribution will be permitted if they are approved by the Food and Drug Administration and the State authority. Prior to any approval of an alternative method of distribution, there will be consultation with the Drug Enforcement Administration, Department of Justice, to assure compliance with its regulations regarding controlled substance distribution.

(2) Information regarding approved programs and hospitals. The Food and Drug Administration will provide manufacturer and the public with names and locations of programs and hospitals that have been approved to receive shipments of narcotic drugs for narcotic addiction treatment. All information contained in the forms required by Paragraph (k) of this section is available for public disclosure, except the names or other identifying information.

(3) Acceptance of delivery. Delivery shall only be made to a licensed practitioner or a licensed pharmacist employed at the facility. At the time of delivery, the licensed practitioner or licensed pharmacist shall sign for the drugs and place his or her specific title and identification number on any invoice. Copies of these signed invoices shall be kept by the manufacturer.

(k) Program forms. The program sponsor must ensure that the following forms are completed by the proper program staff and submitted to the appropriate State authority and the Division of Scientific Investigations, Regulatory Management Branch (HFD-342), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Forms are available upon request from the Regulatory Management Branch (HFD-352) at the same address.

FORM

FDA-2632	Application for Approval of Use of Methadone in a Treatment Program
FDA-2633	Medical Responsibility Statement for Use of Methadone in a Treatment Program
FDA-2635	Consent to Methadone Treatment
FDA-2636	Hospital Request for Methadone Detoxification Treatment

(Approved by the Office of Management and Budget under Number 0910-0140)

[54 FR 8960, Mar. 2, 1989; 54 FR 12531, Mar. 27, 1989]

Appendix B—Guidance on the Use of Methadone in Maintenance and Detoxification Treatment of Narcotic Addicts

March 1989

Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

National Institute on Drug Abuse
Alcohol, Drug Abuse, and Mental Health Administration
Department of Health and Human Services

Appendix B

For further information regarding the guidance document, please contact

Food and Drug Administration
Center for Drug Evaluation and Research
Regulatory Management Branch (HFD-342)
5600 Fishers Lane
Rockville, MD 20857
301-295-8029

Introduction

FDA and NIDA regulation of the medical use of methadone began with Congress' passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513). Section 4 of this act instructed the Secretary of Health, Education, and Welfare to determine "appropriate methods of professional practice in the medical treatment of * * * narcotic addiction."

The legislative history of the act recognized that, historically, practitioners ran a significant risk of criminal prosecution under the Harrison Act of 1914 if they used a narcotic drug in the treatment of drug addiction. Congress referred to the Supreme Court's holding in *Linder* v. *United States*, 268 U.S. 5, 45 S.Ct. 446, 69 L.Ed. 819 (1925) that prescribing "in the ordinary course and in good faith, [a quantity of a narcotic drug] for relief of conditions incident to addiction" was not violative of Federal law. Congress also pointed out that the Bureau of Narcotics' (a predecessor of the Drug Enforcement Administration (DEA)) regulations were, apparently, not in accord with the Court's language. In 1970, the Bureau's regulations stated:

> An order purporting to be a prescription issued to an addict or habitual user of narcotics, not in the course of professional treatment but for the purpose of providing the user with narcotics sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and intent of the [Harrison] Act; and the person filling such an order, as well as the person issuing it, may be charged with violation of the law.

26 CFR 151.392 (1970)

Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970 to clarify this confusing situation. Congressional intent was clear that practitioners who complied with the standards prescribed under section 4 would be assured that their action would not lead to prosecution under the Controlled Substances Act (21 U.S.C. 801 et seq.).

In the early 1970's, diversion of methadone from legitimate commerce into the illegal marketplace was becoming a serious problem. Congress wished neither to ignore this diversion nor to eliminate methadone as a treatment for narcotic drug addiction. Therefore, Congress passed the Narcotic Addict Treatment Act of 1974 (Pub. L. 93-281, 88 Stat. 124), which allowed methadone to be dispensed for detoxification and maintenance only by practitioners who held a registration with DEA to do so. In order for a practitioner to obtain the registration, FDA had to determine that the practitioner was complying with the standards that were established under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Over the intervening years, FDA and NIDA have issued a regulation setting forth the conditions under which narcotic drugs could be dispensed for the treatment of drug addiction, and establishing methadone as the only narcotic drug approved for such a use.

Over the years, the regulation accumulated language that recommended certain practices in addition to requiring other practices. In order to clarify matters, the agencies have issued this guidance document. Most of the provisions are "recommended practices" originally contained in the former regulation, while other provisions were formerly mandatory provisions that are being reissued as recommendations. Certain recommendations in this guidance document are new.

This guidance document is intended to provide recommendations for providing medical and other services in addition to the regulation under 21 CFR 291.505. Following these recommendations should facilitate treatment for narcotic addicts. This guidance document does not represent the formal legal opinion of either FDA or NIDA.

This guidance document and the regulation contained in 21 CFR 291.505 are not meant to preclude States from regulating the practice of medicine in the treatment of narcotic drug addicts. States are free to provide additional requirements for practitioners dispensing methadone for treatment of narcotic addicts. The recommendations of the agencies follow:

Services

Required medical services and counseling, rehabilitative, and other social services (e.g., vocational and educational guidance, employment placement) should normally be made available directly by the sponsor at the primary outpatient facility, but the program sponsor may enter into a formal agreement, which must be documented (see 21 CFR 291.505(b)(2)(iii)), with private or public agencies, organizations, or institutions for these services to be provided on site or elsewhere. Such facilities should be easily accessible to the patient. The patient's progress at the referral agency should be periodically updated.

Hospital Affiliation

If a program is not physically located within a hospital that has agreed to provide any needed medical care for drug-related problems for the program's patients, there should be a formal, documented agreement between the program sponsor and a responsible official of a licensed and accredited hospital demonstrating that hospital care, including emergency, inpatient, and ambulatory care, is fully available to any patient who may need it for such problems. It is suggested that the program sponsor enter into an agreement with the hospital official to provide general medical care for patients. Neither the program sponsor nor the hospital is required to assume financial responsibility for the patient's medical care.

Medication Units

Medication units should normally be located at some distance from the program's primary facility and other medication units so as to serve a separate and distinct geographic area. The enrollment in a medication unit should be of reasonable size in relation to the space available for treatment.

Current Physiological Dependence

In determining current physiologic dependence, the physician should consider signs and symptoms of intoxication, a positive urine specimen for a narcotic drug, and old or fresh needle marks. Other evidence of current physiologic dependence may be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupilary [sic] dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during the initial period of hospitalization or while the person is an outpatient undergoing diagnostic evaluation (e.g., medical and personal history, physical examination, and laboratory studies). Increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely but possible that a person could be currently dependent on narcotic drugs without having a positive urine test for narcotics. Conversely, it is possible that a person could have a positive urine test for narcotics and not be currently physiologically dependent. Thus, a urine sample that is positive for narcotics is not a requirement for admission to detoxification or maintenance treatment.

Drug Screening Urinalysis

The person(s) responsible for the program who uses the results of presumptive urinalysis for patient management should show evidence of reasonable access to confirmatory laboratory analysis for use on occasions when this is necessary, e.g., for intake urine testing on all prospective methadone patients, for any loss of patient privileges based on urinalysis, and for indicating frequency of use of other drugs not detectable by a screening method.

After the initial drug screening urinalysis, urine specimens for each patient should be collected and analyzed on a randomly scheduled basis at least monthly. More frequent testing for a specific drug(s) and for a specific person should occur when clinically indicated as determined by the reasonable clinical judgment of the medical director. Results of urine testing should be used as one clinical tool for the purposes of diagnosis, and in the determination of treatment plans, as well as used as one technique for overall program evaluation by monitoring patient drug-using patterns before and during treatment.

Contents of Medical Evaluation

The following laboratory examinations should be conducted for each patient on admission to a program in addition to the required examinations stated in § 291.505(d)(3)(i):

(1) Complete blood count and differential;

(2) Routine and microscopic urinalysis;

(3) Liver functions profile, e.g., SGOT and SGPT.

(4) When the tuberculin skin test is positive, a chest X-ray or other appropriate tests;

(5) Hepatitis B surface antigen (HBsAg) testing;

(6) When clinically indicated, an EKG;

(7) When appropriate, pregnancy test and a Pap test; and

(8) Other tests when clinically indicated.

When a person is readmitted to a program, it is recommended that the decision determining the appropriate laboratory tests to be conducted be based on the intervening medical history and a physical examination.

Admission Evaluation

A patient's history should include information relating to his or her psychosocial, economic, and family background, and any other information deemed necessary by the program that is relevant to the application or that may be helpful in assessing the resources, e.g., psychological, economic, educational, and vocational strengths and weaknesses, that a patient brings to the treatment setting. Each program should establish its own methods for measuring those strengths and weaknesses to assess the severity of the patient's problem, establish realistic treatment goals, and develop an appropriate treatment plan to achieve these goals. Such assessments should be made on admission or as soon as the patient is stable enough for appropriate interviewing. Treatment plans should reflect individualization geared to the patient's needs.

Initial Treatment Plan

The short-term goals contained in the initial treatment plan should be designed to expect completion within a finite time period, e.g., 90 to 180 days.

The information contained in the initial treatment plan should be in sufficient detail to demonstrate that each patient has been assessed and that the services provided are based on the patient assessment findings and the available program and community services.

Patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables, e.g., patient resources, available program, and community services. It is not the intent of 21 CFR 291.505 or this guidance document to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

Periodic Treatment Plan Evaluation

Changes made to a treatment plan should be fully explained to the patient.

Pregnant Patients

If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures, i.e., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it.

Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued methadone treatment is deemed necessary. Detoxification treatment is not recommended for a pregnant patient.

Staffing Level

Programs that are not treating a large number of patients in maintenance treatment with a once weekly clinic visit schedule should maintain a staffing level ratio of at least 1 counselor to 50 patients.

Initial Dose

The initial dose of methadone should be given in an amount considered sufficient to control or mitigate abstinence symptoms concomitant to withdrawal of narcotic drugs. Currently, there is no absolutely reliable method available to determine narcotic tolerance levels. Thus, determination of the optimum initial dose is made on a case-by-case basis. Methadone dosages that are lower than the patient's current level of narcotic tolerance may result in the patient's experiencing withdrawal symptoms. Dosages sufficiently greater than the current level of narcotic tolerance can result in central nervous system depression, coma, and death. Therefore, it is important that the initial dose be adjusted individually to the narcotic tolerance of the patient. If the patient has been a heavy user of heroin up to the day of admission, he or she may require an initial dose of 15 to 30 milligrams with additional smaller increments 4 to 8 hours later. It is recommended practice that if the patient enters treatment with little or no narcotic tolerance (e.g., recently released from jail or using poor quality heroin), the initial dose be one-half these quantities. If there is any doubt, the smaller dose should be used initially and the patient kept under observation; if the symptoms of abstinence are distressing, an additional 5- to 10-milligram dose should be administered as needed. Subsequently, the dosage should be adjusted individually as tolerated and required. The stabilization dose frequently, but not necessarily, is higher than

the dose needed to reduce withdrawal severity. The usual range of methadone maintenance dosages in the country today is between 40 and 100 milligrams daily.

Maintenance Dosage

The physician should regularly review each patient's dosage level, carefully considering either increasing or decreasing the dosage as indicated. It should be noted that according to the official approved labeling, therapeutic doses of meperidine have precipitated severe reactions in patients currently receiving monoamine oxidase inhibitors or those who have received such agents within 14 days. Similar reactions have not yet been reported with methadone, but if the use of methadone is necessary in such patients, it is recommended that a sensitivity test be performed in which repeated small incremental doses are administered over the course of several hours while the patient's condition and vital signs are under careful observation. Likewise, physicians should also be aware that according to the official approved labeling, concurrent administration of rifampin may possibly reduce the blood concentration of methadone to a degree sufficient to produce withdrawal symptoms. The mechanism by which rifampin may decrease blood concentrations of methadone is not fully understood, although enhanced microsomal drug-metabolized enzymes may influence drug disposition.

Methadone Formulation

The liquid for methadone vehicle should be nonsweetened and should contain a preservative so that the program may instruct patients to keep take-home methadone out of the refrigerator to try to minimize the likelihood of accidental overdoses by children or fermentation of the vehicle.

Take-Home Dose

When considering patient responsibility in handling methadone, the program physician should either consult with, or consider the recommendations of, the staff members most familiar with the relevant facts about the patient involved.

Initial Detoxification Dose

The recommended initial dose in detoxification treatment is 15 to 20 milligrams.

Discontinuation of Methadone Use

Involuntary termination from treatment. The person(s) responsible for a program should develop and post prominently about the program premises at least one copy of a written policy establishing criteria for involuntary termination from treatment. This policy should describe patients' rights as well as the responsibilities and rights of the program staff. At the time a patient enters treatment, an appropriate program staff member designated by the person(s) responsible for the program should inform the patient where the copy of the policy is posted and should inform him or her of the reasons which he or she might be terminated from treatment, his or her right under the involuntary termination procedure, and the fact that information about him or her shall be kept confidential in accordance with 42 CFR Part 2.

Voluntary withdrawal from methadone use. As with most types of medical treatment that require chronic daily administration of medication, patients in methadone treatment should be evaluated periodically regarding the risks and benefits of continuing the medication. For some, the eventual withdrawal from methadone is a realistic goal. However, years of experience demonstrate that for others this goal is not yet realistic, even though these patients show vocational, educational, and psychosocial improvement, and are productive members of society. Research and clinical experience have not yet identified all the critical variables that determine when a patient can be successfully withdraw from methadone and remain drug free. Thus, the determination to withdraw voluntarily from methadone maintenance is empirical and is left to the patient and the reasonable clinical judgment of the physician. Upon reaching a drug-free state, the patient should be encouraged to remain in the program for as long as the program considers it necessary to ensure stability in the drug-free state. The frequency of required program visits for patients for drug-free state may be adjusted at the discretion of the medical director.

Appendix C—List of DEA Regulations Governing Narcotic Treatment Programs

Note to reader: Only those Parts 1301-1307 that apply specifically to methadone maintenance treatment programs are provided in this section. However, the reader is advised to review the DEA regulations in their entirety, as other parts may impact on compliance issues.

§ 1301.22 (a)(6),(11)	Separate registration for medication units and compounders
§ 1301.29	Provisional registration
§ 1301.71 through 1301.74	Security requirements and physical security controls
§ 1304.03 (a),(c),(d)	Records requirements
§ 1304.04 (a),(c),(f)	Maintenance of records and inventories
§ 1304.11 through 1304.14	Requirements for inventories
§ 1304.17	Inventories
§ 1304.21	Continuing records requirements
§ 1304.28	Patient records
§ 1305.08 through 1305.09	Order forms
§ 1307.21	Disposal of controlled substance

CHAPTER II – DRUG ENFORCEMENT ADMINISTRATION DEPARTMENT OF JUSTICE

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

General Information

Sec.

Fees for Registration and Reregistration

Requirements for Registration

Applications for Registration

ACTION ON APPLICATIONS FOR REGISTRATION: REVOCATION OR SUSPENSION OF REGISTRATION

1301.41 Administrative review generally.
1301.42 Action on applications for research in Schedule I substances.
1301.43 Application for bulk manufacture of Sschedule [sic] I and II substances.

1301.44 Certificate of registration; denial of registration.
1301.45 Suspension or revocation of registration.
1301.46 Suspension of registration pending final order.
1301.47 Extension of registration pending final order.
1301.48 Order to show cause.

HEARINGS

1301.51 Hearings generally.
1301.52 Purpose of hearing.
1301.53 Waiver or modification of rules.
1301.54 Request for hearing or appearance; waiver.
1301.55 Burden of proof.
1301.56 Time and place of hearing.
1301.57 Final order.

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

1301.61 Modification in registration.
1301.62 Termination of registration.
1301.63 Transfer of registration.

SECURITY REQUIREMENTS

1301.71 Security requirements generally.
1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.
1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.
1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.
1301.75 Physical security controls for practitioners.
1301.76 Other security controls for practitioners.

EMPLOYEE SCREENING—NON-PRACTITIONERS

1301.90 Employee screening procedures.
1301.91 Employee responsibility to report drug diversion.
1301.92 Illicit activities by employees.
1301.93 Sources of information for employee checks.

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

SOURCE: 36 FR 7778 Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1301.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in Schedules II through V;

(4) Conducting research with controlled substances listed in Schedules II through V;

(5) Conducting instructional activities with controlled substances listed in schedules II through V;

(6) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V, however, pursuant to § 1301.24, employees, agents, or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to § 1305.03;

(7) Conducting research and instructional activities with controlled substances listed in Schedule I;

(8) Conducting chemical analysis with controlled substances listed in any schedule;

(9) Importing controlled substances;

(10) Exporting controlled substances; and

(11) A compounder as defined by § 1301.02(d).

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I shall be authorized to manufacture or import such class if and to the extent that such manufacture or importation is set forth in the research protocol described in § 1301.33 and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to § 1301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person registered or authorized to conduct research with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to import such substances for research purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.26, and to conduct instructional activities with controlled substances;

(6) A person registered to dispense controlled substances listed in Schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he has filed and had approved a research protocol.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 18728, Sept. 21, 1971; 37 FR 15918, Aug. 8, 1972; 38 FR 756, Jan. 4, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973.

EDITORIAL NOTE: For FR Citations affecting § 1301.22, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.29 Provisional registration of narcotic treatment programs; compounders.

(a) All persons currently approved by the Food and Drug Administration under § 310.505 (formerly § 130.44) of this title to conduct a methadone treatment program and who are registered by the Drug Enforcement Administration under this section will be granted a Provisional Narcotic Treatment Program Registration.

(b) The provisions of § 1301.45–1301.57 relating to revocation and suspension of registration, shall apply to a provisional registration.

(c) Unless sooner revoked or suspended under paragraph (b) of this section, a provisional registration shall remain in effect until (1) the date on which such person has registered under this section or has had his registration denied, or (2) such date as may be prescribed by written notification to the person from the Drug Enforcement Administration for the person to become registered to conduct a narcotic treatment program, whichever occurs first.

[39 FR 37984, Oct. 25, 1974]

SECURITY REQUIREMENTS

§ 1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 1301.72–1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 1301.72–1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Diversion Operations Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986]

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2- inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) *Schedules III, IV and V.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in paragraph (a)(1) of this section;

(2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section,

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lay bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BNDD, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in
§ 1301.71(b), (1) through (14);

(8) (i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by 21 CFR 1301.72(a);

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written

determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

(c) *Multiple storage areas.* Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) *Accessibility to storage areas.* The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

[36 FR 18730, Sept. 21, 1971, as amended at 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic]].

EDITORIAL NOTE: For Federal Register citations affecting § 1301.72, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: *Provided,* That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic] and amended at 39 FR 37984, Oct. 25, 1974]

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to § 1301.74(e),

upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) [sic] by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

[36 FR 7778, Apr. 24, 1971; 36 FR 13386, July 21, 1971, as amended at 36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic]]

EDITORIAL NOTE: For Federal Register citations affecting § 1301.74, see the List of CFR Sections Affected in the Finding Aids section of this volume.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

General Information

Inventory Requirements

Continuing Records

Reports

AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(d), 965, unless otherwise noted.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to § 1301.22(b) of this chapter or pursuant to § 1307.11-1307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to acquire separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is required to keep records, as described in § 1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

(c) A registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

(e) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(f) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(g) Notice required by paragraphs (e) and (f) of this section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40523, Oct. 4, 1985; 51 FR 5320, Feb. 13, 1986; 51 FR 26154, July 21, 1986]

§ 1304.04 Maintenance of records and inventories.

(a) Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not excuted [sic] order forms subject to § 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in

Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge.
All notifications must include:

(1) The nature of the records to be kept centrally.

(2) The exact location where the records will be kept.

(3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(4) Whether central records will be maintained in a manual, or computed readable form.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration will expire on September 30, 1980. Registrants who desire to continue maintaining central records will make notification to the local Special Agent in Charge as provided in paragraph (a) of this section.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner

with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

(21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 39 PR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5320, Feb. 13, 1986]

INVENTORY REQUIREMENTS

§ 1304.11 General requirements for inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in [sic] the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in § 1304.18.

(d) A registrant may take an inventory on a date that is within 4 days of his biennial inventory date pursuant to § 1304.13 if he notifies in advance the Special Agent in Charge of the Administration in his area of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

[36 FR 7790, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 47 FR 41735, Sept. 22, 1982]

§ 1304.12 Initial inventory date.

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with §§ 1304.15-1304.19, as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with §§ 1304.15-1304.19, as applicable. In the event a person commences business with no controlled substances on hand, he shall record this fact as his initial inventory.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.13 Biennial inventory date.

Every 2 years following the date on which the initial inventory is taken by a registrant pursuant to § 1304.12, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken (a) on the day of the year on which the initial inventory was taken or (b) on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than 6 months from the biennial date that would otherwise apply or (c) on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory

date or another fixed date, he shall notify the Administration of this election and of the date on which the biennial inventory will be taken.

[36 FR 7791, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.14 Inventory date for newly controlled substances.

On the effective date of a rule by the Administrator pursuant to §§ 1308.48-1308.49, or § 1308.50 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substance shall be included in each inventory made by the registrant pursuant to § 1304.13.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.17 Inventories of dispensers and researchers.

Each person registered or authorized (by § 1301.22(b) of this chapter) to dispense or conduct research with controlled substances and required to keep records pursuant to § 1304.03 shall include in his inventory the same information required of manufacturers pursuant to § 1304.15 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in Schedule I or II, he shall make an exact count or measure of the contents; and

(b) If the substance is listed in Schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

CONTINUING RECORDS

§ 1304.21 General requirements for continuing records.

(a) On and after May 1, 1971, every registrant required to keep records pursuant to § 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in §§ 1304.25 and 1304.26.

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.28 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.22 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;
(2) Strength of substance;
(3) Dosage form;
(4) Date dispensed;
(5) Adequate identification of patient (consumer);

(6) Amount consumed;
(7) Amount and dosage form taken home by patient; and
(8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 1304.24 without reference to § 1304.03.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and part 1401 of this title.
[39 FR 37985, Oct. 25, 1974]

PART 1305—ORDER FORMS

Sec.

AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.
SOURCE: 36 FR 7796, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration, may dispose of any controlled substances listed in Schedule I or II in his possession pursuant to order forms in accordance with § 1307.14 of this chapter;

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person;

(c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, § 1307.11 of this chapter; and

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a controlled substance listed in Schedule I or II to another person registered or authorized to conduct

chemical analysis, instructional activities, or research with such substances pursuant to the order form of the latter person, if such distribution is for the purpose of furthering such chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to offsite narcotic treatment programs only.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971; 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FR citations affecting § 1305.08, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1305.09 Procedure for filling order forms.

(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier, and retain Copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form, except as specified in paragraph (f) of this section.

(d) The supplier shall retain Copy 1 of the order form for his own files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

PART 1307—MISCELLANEOUS

GENERAL INFORMATION

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

DISPOSAL OF CONTROLLED SUBSTANCES

SPECIAL EXEMPT PERSONS

AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant required to make reports pursuant to part 1304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that subpart to the Special Agent in Charge of the Administration in his area.

(2) If the person is a registrant not required to make reports pursuant to part 1304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his area; and

(3) If the person is not a registrant, he shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by the State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

Appendix D—Confidentiality of Alcohol and Drug Abuse Patient Records

Public Health Service, HHS

SUBCHAPTER A—GENERAL PROVISIONS
PART 1—[RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Subpart A—Introduction

Sec.
2.1 Statutory authority for confidentiality of drug abuse patient records.
2.2 Statutory authority for confidentiality of alcohol abuse patient records.
2.3 Purpose and effect.
2.4 Criminal penalty for violation.
2.5 Reports of violations.

Subpart B—General Provisions

2.11 Definitions.
2.12 Applicability.
2.13 Confidentiality restrictions.
2.14 Minor patients.
2.15 Incompetent and deceased patients.
2.16 Security for written records.
2.17 Undercover agents and informants.
2.18 Restrictions on the use of identification cards.
2.19 Disposition of records by discontinued programs.
2.20 Relationship to State laws.
2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.
2.22 Notice to patients of Federal confidentiality requirements.
2.23 Patient access and restriction on use.

Subpart C—Disclosures With Patient's Consent

2.31 Form of written consent.
2.32 Prohibition on redisclosure.
2.33 Disclosures permitted with written consent.
2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.
2.35 Disclosures to elements of the criminal justice system which have referred patients.

Subpart D—Disclosures Without Patient Consent

Subpart E—Court Orders Authorizing Disclosures and Use

AUTHORITY: Sec. 408 of Pub. L. 92-255, 86 Stat. 79, 9s amended by sec. 303 (a), (b) of Pub. L. 93-282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94-237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94-581, 90 Stat. 2852; sec. 509 of Pub. L. 96-88, 93 Stat. 695; sec. 973(d) of Pub. L. 97-35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98-24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290ee-3) and sec. 333 of Pub. L. 91-616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93-282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94-581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98-24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290dd-3).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98-24 to section 527 of the Public Health Service Act which is codified at 42 U.S.C. 290ee-3. The amended statutory authority is set forth below:

§ 290ee-3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or witrhin [sic] those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not nore [sic] than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. (Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98-24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd-3. The amended statutory authority is set forth below:

§ 290dd-3. CONFIDENTIALITY OF PATIENT RECORDS

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treat ..nt of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities

The prohibitions of this section do not apply to any interchange of records-

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. (Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists [sic] under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee-3(f), 42 U.S.C. 290dd-3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621-22, 66 S. Ct. 705, 707-08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee-3(f) and 42 U.S.C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

§ 2.6 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient indentifying [sic] information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official; and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means a person which in whole or in part holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment. For a general medical care facility or any part thereof to be a program, it must have:

(a) An identified unit which provides alcohol or drug abuse diagnosis, treatment, or referral for treatment or

(b) Medical personnel or other staff whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment and who are identified as such providers.

Program director means:

(a) In the case of a program which is an individual, that individual;

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

§ 2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure.* The restrictions on disclosure in these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee-3(c), 42 U.S.C. 290dd-3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under § 2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms "patient" and "program" are defined in § 2.11) if the program is federally assisted in any manner described in § 2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under § 2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in § 2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by § 2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs). [52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgment of the presence of an identified patient in a facility or part of a facility if the facility is not publicy [sic] identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgment does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the, minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors*—(1) *Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless--

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]"; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); [sic] or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These "research privilege" statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilage [sic] granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does

not protect from compulsory disclosure any imformation [sic] which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon threreafter [sic] as the patient is capable of rational communication. [sic] each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser Unless:

(1) The patient consents in writing:

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities. (See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.) (Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) ☐ Request ☐ Authorize:
2. (name or general designation of program which is to make the disclosure)

_____

3. To disclose: (kind and amount of information to be disclosed)

_____

4. To: (name or title of the person or organization to which disclosure is to be made)

_____

5. For (purpose of the disclosure)

_____

6. Date (on which this consent is signed)

_____

7. Signature of patient

_____

8. Signature of parent or guardian (where required)

_____

9. Signature of person authorized to sign in lieu of the patient (where required)

_____

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired:

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.32 Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

Central registry means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Maintenance treatment means the dispensing of anarcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information:

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post-trial release, probation or parole, officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosure Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure; and

(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research;

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

(i) The rights and welfare of patients will be adequately protected; and

(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section;

and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part [sic] payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in § 2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a peer review organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or two investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66 of these regulations.

Subpart E—Court Orders Authorizing Disclosure and Use

§ 2.61 Legal effect of order

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee-3, 42 U.S.C. 290dd-3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application mst [sic] use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order.

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may no contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought with an order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.*

(1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information:* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.65 of these regulations.

PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.

AUTHORITY: Sec. 3(a), Pub. L. 91-513 as amended by sec. 122(b), Pub. L. 93-282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

§ 2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) provides that "[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals." The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General's authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and 21 CFR 1316.21.

(c) The Secretary's regulations on confidentiality of alcohol and drug abuse patient records (42 CFR part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24-1, 42 CFR part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying characteristics of individuals who are the subject of such research.

§ 2a.2 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(b) *Person* means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) *Drug* has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1).

(e) *Controlled drug* means a drug which is included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act (21 U.S.C. 811-812).

(f) *Administer* refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a research subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) *Identifying characteristics* refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) *Psychoactive drug* means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

§ 2a.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described in § 2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the sumission [sic] of a request for DHHS grant or contract assistance, though it is not necessary to request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§ 2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

§ 2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training and experience requirements for major positions not yet filled.

(d) An outline of the research protocol for the project including a clear and concise statement of the purpose and rationale of the research project and the general research methods to be used.

(e) The date on which research will begin or has begun and the estimated date for completion of the project.

(f) A specific request, signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request.

(g) An assurance (1) From persons making application for a Confidentiality Certificate for a research project for which DHHS grant or contract support is received or sought that they will comply with all the requirements of 45 CFR part 46, "Protection of Human Subjects," or

(2) From all other persons making application that they will comply with the informed consent requirements of 45 CFR 46.103(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.110, if it is determined by the Secretary, on the basis of information submitted by the person making application, that subjects will be placed at risk. If a modification of paragraphs (a) or (b) of 45 CFR 46.110 is to be used, as permitted under paragraph (c) of that section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(h) An assurance that if an authorization of confidentiality is given it will not be represented as an endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project.

(i) An assurance that any person who is authorized by the Secretary to protect the privacy of research subjects will use that authority to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects.

(j) An assurance that all research subjects who participate in the project during the period the Confidentiality Certificate is in effect will be informed that:

(1) A Confidentiality Certificate has been issued;

(2) The persons authorized by the Confidentiality Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings whether Federal, State, or local;

(3) If any of the following conditions exist the Confidentiality Certificate does not authorize any person to which it applies to refuse to reveal identifying information concerning research subjects:

(i) The subject consents in writing to disclosure of identifying information,

(ii) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regulations promulgated thereunder (title 21, Code of Federal Regulations), or

(iii) Authorized personnel of DHHS request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See § 2a.7(b));

(4) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects;

(5) The Confidentiality Certificate does not represent an endorsement of the research project by the Secretary.

(k) An assurance that all research subjects who enter the project after the termination of the Confidentiality Certificate will be informed that the authorization of confidentiality has ended and that the persons authorized to protect the identity of research subjects by the Confidentiality Certificate may not rely on the Certificate to refuse to disclose identifying characteristics of research subjects who were not participants in the project during the period the Certificate was in effect. (See § 2a.8(c)). [sic]

§ 2a.5 Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by § 2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

§ 2a.6 Issuance of Confidentiality Certificates; single project limitation.

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide "research" which is within the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application;

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application;

(3) The location of the research project;

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary;

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Director of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating original the [sic] Confidentiality Certificate in accordance with § 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8.

§ 2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 far confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

§ 2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

Appendix E—State and Federal Resources

State Methadone Contact Persons

ALABAMA
Kent Hunt, Director
Division of Substance Abuse Services
Department of Mental Health and Mental Retardation
200 Interstate Park Drive
P.O. Box 3710
Montgomery, AL 36193
Phone: (205) 270-4650
Fax: (205) 240-3195

ALASKA
B.W. Mac Armstrong
Division of Alcoholism and Drug Abuse
AK Department of Health and Social Services
P.O. Box 240249
Anchorage, AK 99524-0249
Phone: (907) 561-4213
Fax: (907) 561-4357

ARIZONA
Ed Zborower
Program Representative for Alcoholism and Drug Abuse
AZ Department of Health Services
Division of Behavioral Health Services
2122 East Highland
Phoenix, AZ 85016
Phone: (602) 381-8995
Fax: (602) 553-9143

CALIFORNIA
Joy Jarfors
Methadone Licensing Branch
Department of Alcohol and Drug Programs
1700 K Street
Sacramento, CA 95814-4037
Phone: (916) 323-2032
Fax: (916) 323-5873

COLORADO
Fred Pottle
Drug Control Administrator
Alcohol and Drug Abuse Division
CO Department of Health
4300 Cherry Creek Drive, S.
Denver, CO 80222
Phone: (303) 692-2930
Fax: (303) 782-4883

CONNECTICUT
John Higgins-Biddle
CT Alcohol and Drug Abuse Commission
999 Asylum Avenue, 3rd Floor
Hartford, CT 06105
Phone: (203) 566-4145
Fax: (203) 566-6055

DELAWARE
John A. Yeatman
Quality Assurance Department
DE Division of Alcoholism, Drug Abuse, and Mental Health
DHSS Campus
1901 N. Dupont Highway
New Castle, DE 19720
Phone: (302) 577-4480
Fax: (302) 577-4405

DISTRICT OF COLUMBIA
Carlessia Hussein
Chief, DC Health Planning and Development
1660 L Street, N.W.
Washington, DC 20036
Phone: (202) 673-7481
Fax: (202) 727-2386

FLORIDA
Phil Emenheiser
Senior Management Analyst
Alcohol and Drug Abuse Program
Department of Health and Rehabilitative Services
1317 Winewood Boulevard
Bldg. 6, Rm.# 450
Tallahassee, FL 32399-0700
Phone: (904) 922-4270
Fax: (904) 487-2239

GEORGIA
Tom Hester
Director
GA Alcohol and Drug Services Section
878 Peachtree Street, N.E.
Suite 319
Atlanta, GA 30309
Phone: (404) 894-6352
Fax: (404) 853-0778

HAWAII
Elaine Wilson
Acting Branch Chief
Alcohol and Drug Abuse Division
HI Department of Health
P.O. Box 3378
Honolulu, HI 96801
Phone: (808) 586-3962
Fax: (808) 586-4016

ILLINOIS
Richard Weisskopf
Supervisor, Compliance and Licensing Unit
Department of Alcoholism and Substance Abuse
100 W. Randolf Street
Suite 5-600
Chicago, IL 60601
Phone: (312) 814-6356
Fax: (312) 814-2419

INDIANA
Johnie L. Underwood
Director
Division of Addiction Services
IN Department of Mental Health
117 East Washington Street
Indianapolis, IN 46204-3647
Phone: (317) 232-7816
Fax: (317) 233-3472

IOWA
Dean Austin
Chief of the Bureau of Licensure
Division of Substance Abuse
IA Department of Public Health
Lucas State Office Building
3rd Floor
Des Moines, IA 50319
Phone: (515) 281-3641
Fax: (515) 281-4958

KANSAS
David Chapman
Administrator of Licensure Certification
KS Alcohol and Drug Abuse Services
300 SW Oakley
Biddle Building
Topeka, KS 66606-1861
Phone: (913) 296-3925
Fax: (913) 296-0511

KENTUCKY
Mac Bell
Division of Substance Abuse
275 East Main Street
Frankfort, KY 40621
Phone: (502) 564-3487

LOUISIANA
Sanford Hawkins
1201 Capitol Access Road
Baton Rouge, LA 70802
Phone: (504) 342-9352
Fax: (504) 342-1384

MARYLAND
Sharon Dow
Chief, Planning and Policy Development
Maryland Alcohol and Drug Abuse Administration
201 West Preston Street, 4th Floor
Baltimore, MD 21201
Phone: (301) 225-6548
Fax: (301) 333-7206

MASSACHUSETTS
Dennis McCarty
Director, Bureau of Substance Abuse Services
Department of Public Health
150 Tremont Street
Boston, MA 02111
Phone: (617) 727-1960 ext. 256
Fax: (617) 727-9288

MICHIGAN
John Willson
Office of Substance Abuse Services
MI Department of Public Health
2150 Apollo Drive
Lansing, MI 48909
Phone: (517) 335-8837

MINNESOTA
Nick Vega Puente
Residential Treatment Coordinator
Chemical Dependency Program Division
MN Department of Human Services
444 Lafayette Road
St. Paul, MN 55155-3823
Phone: (612) 296-4620
Fax: (612) 296-6244

MISSOURI
Michael Couty
Division of Alcohol and Drug Abuse
MO Department of Health
1706 East Elm
Jefferson City, MO 65101
Phone: (314) 751-4942
Fax: (314) 751-7814

NEBRASKA
Malcolm Heard
Director
Division of Alcoholism and Drug Abuse
NE Department of Public Institutions
P.O. Box 94728
Lincoln, NE 68509-4728
Phone: (402) 471-2851, ext.5583
Fax: (402) 479-5145

NEVADA
Gene Rolfe
Program Analyst
Bureau of Alcohol and Drug Abuse
628 Belrose Avenue
Las Vegas, NV 89158
Phone: (702) 486-5194
Fax: (702) 486-5250

NEW JERSEY
Terrence O'Connor
Commissioner
Division of Alcoholism and Drug Abuse and Addiction Services
NJ Department of Health
CN 360, Room 400
Trenton, NJ 08625-0360
Phone: (609) 292-5760
Fax: (609) 292-3816

NEW MEXICO
Geraldine Salazar, Director
Department of Health
Behavioral Health Services Division/SA
Harold Runnels Building
Room 3200 North
1190 Saint Francis Drive
Santa Fe, NM 87501
Phone: (505) 827-2601
Fax: (505) 827-0097

NEW YORK
Addie Corradi
Special Assistant to the Director
New York State Office of Alcoholism and Substance Abuse Services
Executive Park South, Box 8200
Albany, NY 12203-8200
Phone: (518) 457-2062
Fax: (518) 457-5474

NORTH CAROLINA
Doug Baker
Alcohol and Drug Services Section
DMHDDSAS
325 Salisbury Street
Raleigh, NC 27611
Phone: (919) 733-4670
Fax: (919) 733-9455

OHIO
Roger Kenton
Department of Alcohol & Drug Addiction Services
280 North High Street, 12th Floor
Columbus, OH 43215
Phone: (614) 466-3445
Fax: (614) 752-8645

OKLAHOMA
Robert Corley
Alcohol/Drug Program Coordinator
OK Department of Mental Health and Substance Abuse Services
1200 N.E. 13th
Oklahoma City, OK 73152-3277
Phone: (405) 271-7474
Fax: (405) 271-7413

OREGON
Jeffrey Kushner
OR Office of Alcohol and Drug Abuse Programs
1178 Chemeketa Street, N.E., #102
Salem, OR 97310
Phone: (503) 378-2163

PENNSYLVANIA
Cheryl Williams
PA Department of Health
Commonwealth and Forster Streets
Health and Welfare Bldg.
Room 626
P.O. Box 90
Harrisburg, PA 17108
Phone: (717) 783-8675

RHODE ISLAND
Kerry O'Neil
RI Division of Substance Abuse Administration
Department of MHRH
Access Road
P.O. Box 20363
Cranston, RI 02920
Phone: (401) 464-2091

SOUTH CAROLINA
Bill Burnette
SC Commission on Alcohol and Drug Abuse
3700 Forest Drive
Columbia, SC 29204
Phone: (803) 734-9520
Fax: (803) 734-9663

TENNESSEE
Lynn Scarborough
Alcohol and Drug Abuse Services
255 Cordell Hull Building
Nashville, TN 37243-4401
Phone: (615) 741-1921
Fax: (615) 741-0770

TEXAS
Dennis Baker
TX Department of Health
Division of Food and Drug
1100 W. 49th Street
Austin, TX 78756
Phone: (512) 458-7248
Fax: (512) 458-7441

UTAH
Leon PoVey
Director
Department of Social Services
UT Division of Substance Abuse
120 North 200 West
4th Floor
Salt Lake City, UT 84145-0500
Phone: (801) 538-3939
Fax: (801) 538-4016

VIRGINIA
C. Hope Bolger
Office of Substance Abuse Services
VA Department of Mental Health, Mental Retardation, and Substance Services
P.O. Box 1797
109 Governor Street
Richmond, VA 23214
Phone: (804) 786-3906

WASHINGTON
David Curts, Supervisor
Certification Division
Division of Alcohol and Substance Abuse
120 East Union
Suite 108
M.S. EK-14
Olympia, WA 98504
Phone: (206) 753-1274

Appendix E

Federal Agency Contacts Concerning Methadone Policy and Procedure

James Cooper, M.D.
Associate Director for Medical Affairs
National Institute on Drug Abuse
5600 Fishers Lane, Room 10-A-12
Rockwall II, Rockville, MD 20857
Phone: (301) 443-4877
Fax: (301) 443-8674

G. Thomas Gitchel*
Chief, Liaison and Policy Section
Office of Diversion Control
U.S. Department of Justice
Drug Enforcement Administration
Washington, DC 20537
Phone: (202) 307-7297
Fax: (202) 307-8570

Betty Jones**
Chief, Regulatory Management Branch
Division of Scientific Investigations
Food and Drug Administration
7520 Standish Place
Rockville, MD 20855
Phone: (301) 295-8029
Fax: (301) 295-8204

Robert Lubran, M.S., M.P.A.
Senior Advisor for Quality Assurance
Division for State Programs
Center for Substance Abuse Treatment
5600 Fishers Lane
Rockwall II, 8th Floor
Rockville, MD 20857
Phone: (301) 443-8391
Fax: (301) 443-8345

Richard Suchinsky, M.D.
Associate Director for Addictive Disorders and Psychiatric Rehabilitation
Veterans Health Services and Research Administration
Department for Veterans Affairs
810 Vermont Avenue, NW, 141A6
Washington, DC 20420
Phone: (202) 535-7585
Fax: (202) 535-7581

*The first point of inquiry for information about DEA registration should be the appropriate DEA field office.

**The first point of inquiry for information about FDA approval should be the FDA district office.

Federal Resource Panel

John C. Ball, Ph.D.
Senior Scientist & Professor
National Institute on Drug Abuse
Addiction Research Center
Baltimore, MD

Erwin Bloom
Program Analyst
Legislative, Government
& Constituent Relations Branch
Office of Science Policy, Education,
and Legislation
Rockville, MD

Barry S. Brown, Ph.D.
Chief, Community Research Branch
Division of Applied Research
National Institute on Drug Abuse
Rockville, MD

James Callahan, D.P.A.
Executive Vice President
American Society of Addiction
Medicine
Washington, DC 20015

James Cooper, M.D.
Chief, Medical Affairs Branch
Division of Clinical Research
National Institute on Drug Abuse
Rockville, MD

Dorynne Czechowicz, M.D.
Associate Director for Medical and
Professional Affairs
Medical Affairs Branch
Division of Clinical Research
National Institute on Drug Abuse
Rockville, MD

Loretta P. Finnegan, M.D.
Senior Advisor for Women's Issues
National Institute on Drug Abuse
Rockville, MD

Betty Jones
Chief, Regulatory Management Branch
Division of Scientific Investigations
Food and Drug Administration
Rockville, MD

T. Stephen Jones, M.D.
Special Assistant for Substance
Abuse and HIV Prevention
Centers for Disease Control
Department of Health &
Human Services
Atlanta, GA

Howard Lerner, M.P.H.
Deputy Director
Division of Special Populations
Bureau of Health Care Delivery
and Assistance
Health Resources &
Services Administration
Rockville, MD

Linda Lewis, M.A.
Director of Public Policy
National Association State Alcohol
& Drug Abuse Directors
Washington, DC

Raye Litten, Ph.D.
Physiologist & Program Officer
Treatment Research Branch
Division of Clinical & Prevention
Research
National Institute on Alcoholism
& Alcohol Abuse
Rockville, MD

Robert Lubran, M.S., M.P.A.
Senior Advisor for Quality Assurance
Division for State Programs
Center for Substance Abuse Treatment
Rockville, MD

Anna Marsh, Ph.D.
Chief
Quality Assurance And Evaluation
Branch
Division for State Programs
Center for Substance Abuse
Treatment
Rockville, MD

Steven Molinari, J.D., R.Ph.
Regulatory Counsel
Regulatory Affairs Branch
Division of Clinical Research
National Institute on Drug Abuse
Rockville, MD

Joseph O'Neil, M.D.
Chief, HIV/Substance Abuse Branch
Division of Special Populations
Bureau of Health Care Delivery
and Assistance
Health Resources and Services
Administration
Rockville, MD

Mark W. Parrino, M.P.A.
President
American Methadone
Treatment Association, Inc.
New York, NY

Nicholas Reuter
Consumer Safety Officer
Health Assessment Policy Staff
Associate Commissioner for Health
Affairs
Food and Drug Administration
Rockville, MD

William Reinig
Chief Liaison & Policy Branch
Office of Diversion Control
Drug Enforcement Administration
Washington, DC

Lisa Scheckel
Acting Deputy Director
Center for Substance Abuse Treatment
Rockville, MD

Richard Suchinsky, M.D.
Associate Director for
Addictive Disorders & Psychiatric
Rehabilitation
Veterans Health Services and Research
Administration
Department for Veterans Affairs
Washington, DC

Appendix E

Johnnie L. Underwood
Deputy Commissioner
Division of Addictive Services
Indiana Department of Mental Health
Indianapolis, IN

Curtis Wright, M.D.
Medical Officer
Food & Drug Administration
Rockville, MD

Appendix F—Field Reviewers

Cynthia E. Aiken, M.S.
Executive Director
Narcotic Drug Treatment Center Inc.
Center for Drug Problems
Anchorage, AK

Michael E. Amara, R.N.
Assistant Director, Program Management Division
Connecticut Alcohol and Drug Abuse Commission
Hartford, CT

M. Douglas Anglin, Ph.D.
Director
UCLA Drug Abuse Research Center
Los Angeles, CA

G. Dean Austin, M.A.
Chief, Licensure Section
Iowa Department of Public Health
Division of Substance Abuse and Health Promotion
Des Moines, IA

Doug Baker
Chief
Adult Services Branch
Substance Abuse Services Section
Raleigh, NC

John C. Ball, Ph.D.
Senior Scientist and Professor
Addiction Research Center
Baltimore, MD

Jim Baum, M.S., C.C.D.C.
Program Sponsor
Bluegrass East Comprehensive Care Center
Lexington, KY

Mac Bell
Program Administrator
Division of Substance Abuse
Frankfort, KY

Dennis Bobo
Controlled Substances Policy Specialist
State Methadone Authority
Division of Community Services
Madison, WI

Elizabeth R. Brown, M.D.
Director of Neonatology
Associate Professor of Pediatrics
Boston City Hospital
Boston, MA

Sally S. Brown, Ph.D.
Clinical Psychologist
Associate Director
Project Reality
Salt Lake City, UT

Darryl Bruno
Administrator
Dept. of Corrections & Human Services Alcohol and Drug Abuse Division
Helena, MT

Richard Christensen, P.A., C.A.S.
Director of Medical Services
Valle Del Sol Narcotic Treatment Project
Phoenix, AZ

Addie Corradi
Special Assistant to the Director
New York State Office of Alcoholism and Substance Abuse Services
Albany, NY

Michael David Couty
Deputy Director
Department of Mental Health
Division of Alcohol and Drug Abuse
Jefferson City, MO

Dorynne Czechowicz, M.D.
Associate Director for Medical and Professional Affairs
Division of Clinical Research, NIDA
Medical Affairs Branch
Rockville, MD

Helen L. Danser, R.Ph.
Pharmacy Services Program Manager
Division of Mental Health
Department of Mental Health and Mental Retardation Services
Frankfort, KY

James E. Delaney, R.Ph., M.P.H.
Methadone Compliance Coordinator
Substance Abuse Services Section
Georgia Department of Human Resources
Atlanta, GA

David R. Dixon
Treatment Services Coordinator
STEP ONE, Inc.
Winston-Salem, NC

Sharon R. Dow
Chief
Planning and Policy Development
Alcohol and Drug Abuse Administration
Maryland Department of Health and Mental Hygiene
Baltimore, MD

Cynthia E. Dozier, Ph.D.
Consultant
New Paltz, NY

Michael Ezzell
Director, Program Compliance
Texas Commission on Alcohol and Drug Abuse
Austin, TX

Loretta P. Finnegan, M.D.
Senior Advisor on Women's Issues
Office of the Director
National Institute on Drug Abuse,
Rockville, MD

John S. Flint, M.D.
Medical Director
Operation PAR, Inc.
St. Petersburg, FL

Brian M. Foss, M.S.W., LICSW
Vice President
Center for Human Services, Inc.
Health and Substance Abuse Services
New Bedford, MA

Steven Freng
Acting Manager
King County Division of Alcoholism and Substance Abuse Services
Seattle, WA

David R. Gastfriend, M.D.
Chief, Addiction Services
Massachusetts General Hospital
Harvard Medical School
Boston, MA

G. Thomas Gitchel
Chief, Liaison & Policy Section
Office of Diversion Control
Drug Enforcement Administration
U.S. Department of Justice
Washington, D.C.

Jeff Gronstal
Licensure Surveyor
Iowa Department of Public Health
Division of Substance Abuse and Health Promotion
Des Moines, IA

Merrill Herman, M.D.
Chief of Service
Montefiore Medical Center
Bronx, NY

Eugene I. Hoffman
Senior Counselor
Hennepin County Methadone Services
Hennepin County Health Department
Minneapolis, MN

Robert Holden, C.C.D.T.
Program Director
Partners In Drug Abuse, Rehabilitation and Counseling
Washington, DC

Elizabeth Imeson, M.D., M.P.H.
Medical Director
Southbend Counselling Center
Lansing, MI

Paul W. Ingram, M.S.W.
Executive Director
PBA, Inc. - The Second Step
Pittsburgh, PA

Joy Jarfors
Manager, Methadone Licensing Branch
State of California Department of Alcohol and Drug Programs
Sacramento, CA

Oscar Jones, C.S.W., A.C.P., C.A.D.A.C.
Program Director
Lubbock Regional Mental Health and Mental Retardation Center
Lubbock, TX

Robert B. Kahn, Ph.D.
President
San Diego Treatment Services
California Organization of Methadone Providers
San Diego, CA

John Kampersal, M.S.W., LICSW
Clinical Manager
Center for Human Services, Inc.
Health and Substance Abuse Services
New Bedford, MA

Janice F. Kauffman, R.N., M.P.H., C.A.S.
Director, Substance Abuse Treatment Services
North Charles, Inc.
Somerville, MA

Gary J. Koontz, M.A.
Adult Treatment Services Coordinator
Department of Health and Human Services
Bureau of Human Resources
Office of Behavioral Health Services
Division on Alcoholism & Drug Abuse
Charleston, WV

Thomas R. Kosten, M.D.
Associate Professor of Psychiatry
Yale University School of Medicine
Substance Abuse Treatment Unit
New Haven, CT

Roland C. Lamb
Director, Methadone Clinic
Parkside Human Services
Philadelphia, PA

Richard H. Lane
Executive Director
Man Alive Research, Inc.
Baltimore, MD

Howard C. Lerner, M.P.H.
Deputy Director
Division of Special Populations
Program Development
Bureau of Health Care Delivery and Assistance
Health Resources and Services Administration
Rockville, MD

Marilyn LeVee, A.C.S.W.
Supervisor
Southland Counseling Center
Lansing, MI

Linda N. Lewis, B.A., M.A.
Director of Public Policy
National Association of State Alcohol and Drug Abuse Directors
Washington, DC

Charlene Lewis, Ph.D.
Program Analyst
Office of Policy, Planning and Evaluation
Center for Substance Abuse Treatment
Rockville, MD

Raye Z. Litten, Ph.D.
Physiologist and Program Officer
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Rockville, MD

James E. Long
Director
Illinois Department of Alcoholism and Substance Abuse
Springfield, IL

Mitchell B. Mackinem, M.A., N.C.A.C.II
Treatment Consultant
South Carolina Commission on Alcohol and Drug Abuse
Columbia, SC

David J. Mactas
President
Marathon, Inc.
Providence, RI

Janice S. Maehlum, M.A.
Director, Drug Programs
Dede Wallace Center
Madison, TN

Kay Malone, R.N., C.D., M.H.S.
Nursing Supervisor/AIDS Coordinator
Brandywine Counseling, Inc.
Wilmington, DE

Ira J. Marion
Associate Executive Director
Albert Einstein College of Medicine
Division of Substance Abuse
Bronx, NY

Michael Mason, Ph.D.
Clinical Psychologist
Dept. of Public Health and Environmental Services
Government of the Northern Mariana Islands
Saipan, MP

Myrene McAninch, Ph.D., F.A.C.A.T.A
President
Healthcare Quality Improvement, Inc.
Seattle, WA

Michael J. McCann, M.A.
Administrative Director
Matrix Center, Inc.
Woodland Hills, CA

John J. McCarthy, M.D.
Executive and Medical Director
Bi-Valley Medical Clinic
Sacramento, CA

Linda McCorkle
Treatment Consultant
Department of Health
Bureau of Alcohol and Drug Abuse
Nashville, TN

Paul McLaughlin
Executive Director
The Hartford Dispensary
345 Main Street
Hartford, CT 06106

Yuji Mesubed, M.O.
Minister of Health
Republic of Palau
Koror, Palau, PW

Joel L. Millard
Executive Director
Project Reality
Salt Lake City, UT

Robert B. Millman, M.D.
Saul P. Steinberg Distinguished Professor of Psychiatry and Public Health
Cornell University Medical College
New York, NY

Stephen P. Molinari, J.D., R.Ph.
Regulatory Counsel
Medical Affairs Branch
Division of Clinical Research
National Institute on Drug Abuse
Rockville, MD

Nina Peskoe Peyser, M.B.A.
Executive Director
Chemical Dependency Institute
Beth Israel Medical Center
New York, NY

La Dema Poppa, M.S.N., R.N.
Clinical Nurse Specialist
Richard L. Roudebush Veterans Affairs Medical Center
Chemical Dependency Treatment Section
Indianapolis, IN

Frederick C. Pottle
Drug Control Administrator - Program Administrator
Alcohol and Drug Abuse Division
Colorado Department of Health
Denver, CO

Leon PoVey, M.S.W.
Director
Utah State Division of Substance Abuse
Salt Lake City, UT

Michael J. Prejean, M.D.
Medical Director
Division of Alcohol and Drug Abuse
State of Louisiana
Carencro, LA

Geraldine Salazar
Division Director
Behavioral Health Services Division
Sante Fe, NM

Marianne L. Scheck, R.N.
Registered Nurse, Certified Alcohol and Drug Counselor
Marion County Drug Treatment Program
Salem, OR

Sidney H. Schnoll, M.D., Ph.D.
Professor of Internal Medicine
and Psychiatry
Medical College of Virginia
Richmond, VA

Karen Schrock
Administrator
Center for Substance Abuse Services
Michigan Department of Public Health
Lansing, MI

Edward C. Senay, M.D.
Professor of Psychiatry
Chicago, IL

Craig V. Showalter, M.D.
Addiction Medicine Specialist
The Breakers
Chicago, IL

Sandra R. Smith
Executive Vice President/COO
STEP ONE, Inc.
Winston-Salem, NC

Ronald G. Speckmann
Director
Office of Substance Abuse
Augusta, ME

Elizabeth Stanley, M.P.H.
Chief Deputy Director
Methadone Licensing Branch
Alcohol & Drug Programs
Sacramento, CA

Ken Stark
Director
Division of Alcoholism and
Substance Abuse
Washington Department of Social
and Health Services
Olympia, WA

Craig S. Stenning
Executive Director
CODAC
Cranston, RI

Carolyn Suchecki, R.N.
Quality Assurance Coordinator
Connecticut Alcohol and
Drug Abuse Commission
Hartford, CT

Richard T. Suchinsky, M.D.
Associate Director for
Addictive Disorders and Psychiatric
Rehabilitation
Department of Veterans Affairs
Washington, DC

Norman Teeter
Director
Raleigh Professional Associates
Memphis, TN

Paul Tierney
Program Coordinator
Bureau of Substance Abuse
Department of Public Health
Boston, MA

Michael Townsend, M.S.S.W
Director
Division of Substance Abuse
Department for Mental Health and
Mental Retardation Services
Frankfort, KY

Sari Trachtenberg, M.A., C.A.C.
Clinical Coordinator
Achievement Through Counseling
and Treatment II
Philadelphia, PA

Wendell R. Turner
Director of Methadone
Policy and Services
National Association of State Alcohol
and Drug Abuse Directors
Washington, DC

William Wasserman, M.P.H.
Administrator, Integrated Substance
Abuse/Primary Care Project
Montefiore Medical Center
Bronx, NY

Cheryl D. Williams
Director, Division of Licensing
Commonwealth of Pennsylvania
Department of Health
Office of Drug & Alcohol Program
Harrisburg, PA

Ken Willinger, Ph.D.
Clinical Psychologist
State of Hawaii Alcohol & Drug
Abuse Division
Honolulu, HI

John Willson
State Methadone Authority
Michigan Department of Public Health
Office of Substance Abuse Services
Lansing, MI

Larry J. Worley, M.A., C.S.A.C.
Director of Clinical Services
Nevada Treatment Centers
Las Vegas, NV

Janet K. Zwick
Director
Division of Substance Abuse and
Health Promotion
Iowa Department of Public Health
Des Moines, IA

DHHS Publication No. (SMA) 93-1991
Substance Abuse and Mental Health Services Administration
Printed 1993

SAMHSA